Women's Health Programs Policy and Procedure Manual

Texas Health and Human Services Commission

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TEXAS
Health and Human Services

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SECTION I – INTRODUCTION

CHAPTER 1: PROGRAM AUTHORIZATION

Purpose of the Manual

The Women's Health Programs (WHP) Policy Manual is a guide for contractors who deliver Breast and Cervical Cancer Services (BCCS), the Family Planning Program (FPP), and Healthy Texas Women (HTW) services in Texas under the Women's Health Programs contract. The policy manual has been structured to provide contractor staff with information needed to comply with program requirements.

Program Authorization

BCCS, FPP, and HTW are authorized generally by Texas Government Code § 531.0201(a)(2)(C), which transferred client services functions performed by the Texas Department of State Health Services to Texas Health and Human Services Commission (HHSC), and Texas Government Code § 531.0204, which required the HHSC Executive Commissioner to develop a transition plan which includes an outline of HHSC's reorganized structure and a definition of client services functions.

BCCS is authorized by federal law 42 USC § 300k--300n-5 through the Centers for Disease Control and Prevention (CDC) via the National Breast and Cervical Cancer Early Detection Program (NBCCEDP).

Federal Medicaid law gives states the option to provide Medicaid assistance to women who were screened through the Centers for Disease Control and Prevention's (CDC) National Breast and Cervical Cancer Early Detection Program (NBCCEDP) and found to have breast or cervical cancer.[1]

Texas provides Medicaid coverage to eligible women diagnosed with breast or cervical cancer by a BCCS program contractor.[2,3]

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[1] 42 U.S.C. §1396a(aa).

[2] Human Resources Code §32.024 (y) and (y-1).

[3] In 2007, the 80th Texas Legislature adopted Human Resources Code §32.024 (y-1), authorizing any health care provider to refer eligible women in need of treatment for breast or cervical cancer to Medicaid. Effective September 1, 2007, any woman diagnosed with breast or cervical cancer and meets all eligibility requirements, as determined by BCCS policy for Medicaid for Breast and Cervical Cancer (MBCC), may receive Medicaid services.

Compliance

Federal and state laws related to reporting abuse, operation of health facilities, professional practice, insurance coverage, and similar topics also impact women's health and family planning services. Contractors are required to be aware of and comply with current laws.

Title XIX – Medicaid (Title XIX of the Social Security Act) was created by Congress in 1965. All organizations that receive WHP funding are required to be enrolled providers of services to Medicaid-eligible women and men. (Federal regulation: Title XIX, Social Security Act, [42 USC § 1396-1396v et. seq.] Grants to States for Medical Assistance Programs).

FPP and HTW providers must also follow policies and procedures as established by the Texas Medicaid Program in the Texas Medicaid Provider Procedures Manual (TMPPM).

HTW is a successor program to the WHP and the former Medicaid Women's Health Program, and is therefore subject to Texas Human Resources Code §32.024(c-1).

Program Description

BCCS provides women with low incomes access to quality breast and cervical cancer screening and diagnostic services.

FPP provides comprehensive family planning services to reduce unintended pregnancies, positively affect future pregnancies, and improve the health status of women and men.

HTW provides women's health and family planning services at no cost to eligible women in Texas to increase access to women's health and family planning services to avert unintended pregnancies, positively affect the outcome of future pregnancies, and positively impact the health and well-being of women and their families.

Rules

The state rules for program services can be found at:

- BCCS - Texas Administrative Code (TAC), Title 25 Part 1, Chapter 61, Subchapter C;

- FPP – Texas Administrative Code (TAC), Title 1, Part 15, Chapter 382, Subchapter B.
- HTW - Texas Administrative Code (TAC), Title 1, Part 15, Chapter 382, Subchapter A.

Funding

BCCS services are funded by a federal CDC cooperative agreement, federal TANF to Title XX funds, and State General Revenue.

FPP services are funded by State General Revenue and federal TANF to Title XX funds.

HTW services are funded by State General Revenue.

Definitions

The following words and terms, when used in this manual, have the following meanings.

Applicant – A person applying to receive services under the Women's Health Programs, including a current client who is applying to renew.

Affiliate – (A) An individual or entity that has a legal relationship with another entity, which relationship is created or governed by at least one written instrument that demonstrates: (i) common ownership, management, or control; (ii) a franchise; or (iii) the granting or extension of a license or other agreement that authorizes the affiliate to use the other entity's brand name, trademark, service mark, or other registered identification mark.

Barrier to Care – A factor that hinders a person from receiving health care (i.e., distance, lack of transportation, documentation requirements, co-payment amount, etc.).

Breast and Cervical Cancer Services (BCCS) – A program administered by HHSC that provides breast and cervical cancer screening services to low-income uninsured and underinsured women.

Centers for Disease Control and Prevention (CDC) – Federal agency responsible for protecting the health and safety of all Americans, and for providing essential human services.

Cervical Dysplasia (CD) Management and Treatment Services – Management and treatment services provided to women with biopsy-confirmed

cervical dysplasia.

Client – A person who has been screened and determined to be eligible for the program.

Compass 21 – TMHP's automated claims processing system used to process claims for services delivered to FPP and HTW clients.

Confidentiality – The state of keeping information private and not sharing it without permission.

Consultation – A type of service provided by a healthcare provider with expertise in a medical or surgical specialty, and who, upon request of another appropriate healthcare provider, assists with the evaluation and/or management of a patient.

Contraceptive Method – Any birth control option approved by the United States Food and Drug Administration, except for emergency contraception.

Contractor –An entity that HHSC has contracted with to provide services. The contractor is the responsible entity even if there is a subcontractor involved who provides the services. May also be referred to as a grantee.

Co-payment (co-pay) – Money collected directly from clients for services.

Cost Reimbursement –The funding mechanism for qualified organizations used for support services that enhance HTW and FPP fee-for-service client service delivery.

Covered Service – A medical procedure for which the program will reimburse an enrolled healthcare provider.

Diagnosis –The recognition of disease status determined by evaluating the history of the client and the disease process, and the signs and symptoms present. (Determining the diagnosis may require microscopic (i.e., culture), chemical (i.e., blood tests), and/or radiological examinations (i.e., x-rays).

Diagnostic Services – Activities related to the diagnosis made by a physician, advanced practice nurse or physician assistant, which may also be performed by nurses or other health professionals.

Diagnostic Studies or Diagnostic Tests – Tests ordered by the client's health care practitioner(s) to evaluate a client's health status for diagnostic purposes.

Disease Surveillance - Periodic monitoring for disease progression to quickly

identify and treat pre-cancerous and cancerous conditions.

Dual-Eligible – Eligible for programs providing the same or similar services.

Eligibility Date - Date the contractor determines a person eligible for the program.

Elective Abortion - The intentional termination of a pregnancy by an attending physician who knows that the female is pregnant, using any means that is reasonably likely to cause the death of the fetus. The term does not include the use of any such means to terminate a pregnancy that resulted from an act of rape or incest; in a case which a female suffers from a physical disorder, physical disability, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy, that would, as certified by a physician, place the female in danger of death or risk of substantial impairment of a major bodily function unless an abortion is performed; or in a case in which a fetus has a life-threatening physical condition that, in reasonable medical judgement, regardless of the provision of life-saving treatment, is incompatible with life outside the womb.

Eligible Immigrant - A Qualified Alien of the United States with 40 countable qualifying quarters or earnings, if five years have passed since the legal date of entry as outlined in the Texas Administrative Code (TAC) Title 1, Part 15, Chapter 382, Subchapter A. The applicant must meet the residency standards defined in 1 TAC §366.513.

Family Planning Program - A non-Medicaid program used to provide family planning services to low-income women and men who are Texas residents.

Family Planning Services - Educational or comprehensive medical activities that enable clients to determine freely the number and spacing of their children and to select the means by which this may be achieved.

Federal Poverty Level (FPL) - The household income guidelines issued annually and published in the Federal Register by the United States Department of Health and Human Services.

Fee-for-service – Payment mechanism for services that are reimbursed on a set rate per unit of service (also known as unit rate).

Fiscal Year (FY) – State fiscal year, September 1 through August 31.

Good Faith Effort – Making at least three (3) separate documented attempts to obtain treatment for clients with a pre-cancerous or cancerous breast or cervical

diagnosis who do not meet the eligibility criteria for BCCS Cervical Dysplasia and/or Medicaid for Breast and Cervical Cancer (MBCC).

Health and Human Services Commission (HHSC) – the administrative agency established under Chapter 531, Texas Government Code or its designee.

Health-Care Provider – A physician, physician assistant, nurse practitioner, clinical nurse specialist, certified nurse midwife, federally qualified health center, family planning agency, health clinic, ambulatory surgical center, hospital ambulatory surgical center, laboratory, or rural health center.

HTW Provider – A health care provider that is qualified to perform covered HTW services. An HTW provider may be contracted with HHSC to provide additional services.

Health Screening – The provision of tests, (e.g., blood glucose, serum cholesterol, fecal occult blood) as a means of determining the need for intervention and perhaps more comprehensive evaluation.

Health Service Region (HSR) – Counties grouped within specified geographic service areas throughout the state. https://www.dshs.texas.gov/regions/state.shtm

Healthy Texas Women – HTW is a state-funded program administered by HHSC to provide uninsured women with women's health and family planning services such as women's health exams, health screenings, and birth control.

Family Composition/Household – A person living alone or a group of two or more persons related by birth, marriage (including common law) or adoption, who reside together and who are legally responsible for the support of the other person.

Informed Consent – The process by which a health care provider ensures that the benefits and risks of a diagnostic or treatment plan, the benefits and risks of other appropriate options, and the benefits and risks of taking no action are explained to a patient in a manner that is understandable to that patient and allows the patient to participate and make sound decisions regarding his or her own medical care.

In-reach – Activities that are conducted with the purpose of informing and educating existing clients within an organization about services they are not receiving but may be eligible to receive.

Intended pregnancy – Pregnancy a woman reports as timed well or desired at the time of conception.

Long-Acting Reversible Contraception (LARC) – Methods of birth control that provide effective contraception for an extended period without requiring user action. LARC include intrauterine devices (IUD) and subdermal contraceptive implants.

Medicaid – The Texas Medical Assistance Program, a joint federal and state program provided in Texas Human Resources Code Chapter 32, and subject to Title XIX of the Social Security Act, 42 U.S.C. §1396, et seq.

Medicaid for Breast and Cervical Cancer (MBCC) – Medicaid program that provides access to cancer treatment services for qualified women.

Med-IT® - Medical Information Tracking System

Minimum Data Elements (MDE) – A set of standardized data elements used to collect demographic and clinical information on women screened with NBCCEDP funds.

Minor – A person under 18 years of age who has never been married and never been declared an adult by a court (emancipated).

Memorandum of Understanding MOU – A written document that represents the agreement of the parties regarding the subject matter of the document; it does not usually involve transfer of funds in exchange for services but may document transfer of funds required by statute. Because the underlying agreement may or may not constitute a contract. It is generally considered a less formal way of evidencing an agreement and is ordinarily used in state government only between or among state agencies or other governmental entities.

National Breast and Cervical Cancer Early Detection Program (NBCCEDP) – A federal program administered by the CDC that awards funds to Texas BCCS and other state and tribal grantees to help women who are low-income, uninsured, and underserved gain access to screening for early detection of breast and cervical cancer.

Outreach – Activities that are conducted with the purpose of informing and educating the community about services and increasing the number of clients.

Patient Navigation – Individualized assistance provided to women to help overcome barriers and facilitate timely access to quality screening and diagnostic services, as well as initiation of timely treatment for those diagnosed with cancer.

Point of Service – The location where an individual can receive services.

Preventive Health Care Services – Medical care that focuses on disease prevention and health maintenance, including early diagnosis of disease, discovery, and identification of people at risk of development of specific problems, counseling, and other necessary intervention to avert a health problem. Included are screening tests, immunizations, risk assessments, health histories, and baseline physicals for early detection of disease and restoration to a previous state of health, and prevention of further deterioration and/or disability.

Program Income – Monies collected directly by the contractor/provider for services provided under the contract award (i.e., patient co-pay fees, if applicable).

Readiness – The ability to meet program and contractual requirements.

Referral – The process of directing or redirecting (as a medical case or a person) to an appropriate specialist or agency for information, help, or treatment. A referral does not require a written MOU, vendor agreement, or subcontract.

Referral Agency – An agency that will provide a service for the client that the contractor or one of its vendors does not provide.

Subcontract – A written agreement between the original contractor and a third party to provide a specified part of the work or materials required in the original contract.

Subcontractor – An entity with a written agreement established between itself and the original contractor to provide a specified part of the work or materials required in the original contract.

Subrecipient – a recipient of a subaward from a pass-through entity to carry out the terms of the award, and whose performance is measured in relationship to the award's objectives.

Texas Medicaid and Healthcare Partnership (TMHP) – The claims administrator for FPP and HTW under contract with HHSC.

Texas Resident – A person who resides within the geographic boundaries of the state.

Underinsured – Inadequate access to insurance. Underinsured clients may have coverage which allows for preventive (screening) services but is limited or cost-prohibitive for additional workup.

Unintended Pregnancy – pregnancy that female reports as either mistimed or undesired at the time of conception

Unduplicated Client – Clients enrolled in any of the Women's Health Programs are counted only one time during the program's fiscal year, regardless of the number of visits, encounters, or services they receive (e.g., one person seen four times during the year is counted as one unduplicated client.)

Vendor – An entity selected by the contractor to deliver goods, items, and services that the contractor does not or is unable to provide. A vendor relationship may be established by a written MOU or vendor agreement.

Vendor Agreement– a written agreement between the original contractor and a third party to deliver goods, items, and services that the contractor does not or is unable to provide.

Acronyms

Acronym	Full Name
ADA	Americans with Disabilities Act
AED	Automated External Defibrillator
AGC	Atypical Glandular Cells
AMA	American Medical Association
A/R	Accounts Receivable
ASC-US	Atypical Squamous Cells of Undetermined Significance
BCCS	Breast and Cervical Cancer Services
CAD	Computer Aided-Detection
CAM	Complementary and Alternative Medications
CAP	Corrective Action Plan

CBE	Clinical Breast Exam
CD	Cervical Dysplasia
CDC	Centers for Disease Control and Prevention
CDSB	Contract Development and Support Branch
CHIP	Children's Health Insurance Program
CHW	Community Health Worker
CIHCP	County Indigent Health Care Program
CIN	Cervical Intraepithelial Neoplasia
CLIA	Clinical Laboratory Improvement Amendments
CMS	Centers for Medicare and Medicaid Services
CPR	Cardiopulmonary Resuscitation
CPT	Current Procedure Terminology
DES	Diethylstilbestrol
DHHS	U.S. Department of Health and Human Services
EC	Endocervical
ECC	Endocervical Curettage
EDI	Electronic Data Interchange
EHR	Electronic Health Record
E/M	Evaluation and Management Services
EMR	Electronic Medical Record

EOB	Explanation of Benefit
EPHC	Expanded Primary Health Care
EPT	Expedited Partner Therapy
FDA	Federal Drug Administration
FFS	Fee-for-Service
FP	Family Planning
FPL	Federal Poverty Level
FPP	Family Planning Program
FQHC	Federally Qualified Health Center
FRR	Financial Reconciliation Report
FSR	Financial Status Report
HHSC	Texas Health and Human Services Commission
HIPAA	Health Insurance Portability and Accountability Act
HIV	Human Immunodeficiency Virus
HPV	Human Papillomavirus
HSIL	High-grade Squamous Intraepithelial Lesion
HSR	Health Service Region
HSV	Herpes Simplex Virus
HTW	Healthy Texas Women
IPV	Intimate Partner Violence

IRB	Institutional Review Board
IUC	Intrauterine Contraception
IUD	Intrauterine Device
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
LARC	Long-acting Reversible Contraceptive
LEP	Limited English Proficiency
LSIL	Low-grade Squamous Intraepithelial Lesion
MBCC	Medicaid for Breast and Cervical Cancer
MCH	Maternal and Child Health Services
MDE	Minimum Data Elements
MED-IT®	Medical Information Tracking
MRI	Magnetic Resonance Imaging
NBCCEDP	National Breast & Cervical Cancer Early Detection Program
NILM	Negative for Intraepithelial Lesion or Malignancy
NPI	National Provider Identifier
NPPES	National Plan and Provider Numeration System
OTC	Over the Counter
PAA	Prescriptive Authority Agreement
PDPT	Patient-Delivered Partner Therapy
PHC	Primary Health Care

QA	Quality Assurance
QM	Quality Management
RFP	Request for Proposal
RSDI	Retirement Survivors Disability Income
SDO	Standing Delegation Orders
SSA	Social Security Administration
SSDI	Social Security Disability Income
SSI	Supplemental Security Income
STD	Sexually Transmitted Disease
STI	Sexually Transmitted Infection
TAC	Texas Administrative Code
TANF	Temporary Assistance for Needy Families
TMHP	Texas Medicaid Healthcare Partnership
TMPPM	Texas Medicaid Provider Procedures Manual
TPI	Texas Provider Identifier
USPSTF	United States Preventive Services Task Force
WHP	Women's Health Programs
WIC	Special Supplemental Nutrition Program for Women, Infants & Children
VDP	Vendor Drug Program

SECTION II – ADMINISTRATIVE POLICIES

CHAPTER 1: CLIENT ACCESS

The contractor must ensure that clients are provided services in a timely and nondiscriminatory manner. The contractor must ensure that:

- there is a policy in place that delineates the timely provision of services;
- individuals deemed eligible for each program are provided services as soon as possible - no later than 30 days from initial request;
- minors age 17 and younger are seen as soon as possible, with every effort made to provide an appointment within two weeks of the request;
- individuals who request contraception but cannot be immediately provided a clinical appointment are offered a non-prescription method;
- clinic/reception room wait times are reasonable and do not present a barrier to service;
- all applicable civil rights laws and regulations including Title VI of the Civil Rights Act of 1964, the Americans with Disabilities Act of 1990, the Age Discrimination Act of 1975, and Section 504 of the Rehabilitation Act of 1973, are followed and that services are accessible to persons with Limited English Proficiency (LEP) and speech or sensory impairments at no cost to the person;
- there is a policy in place that requires qualified staff to assess and prioritize a client's needs;
- individuals that cannot be served or cannot receive a specific service are provided a referral;
- funds are managed to ensure that established clients continue to receive services throughout the budget year, including after allocated funds are expended;
- individuals are informed of program services and encouraged to bring required documentation to the initial visit for eligibility processing;
- policies are in place to identify and eliminate possible barriers to client care; and
- an eligible individual seeking Family Planning Program services must not be denied services due to an inability to pay.

CHAPTER 2: ABUSE AND NEGLECT REPORTING

HHSC contractors must be familiar with and comply with state laws governing the reporting of suspected abuse and neglect of children, adults with disabilities, or individuals 65 years of age or older.

To report abuse or neglect, call the Texas Abuse Hotline **800-252-5400**, use the secure website, or call any local or state law enforcement agency for cases that pose an imminent threat or danger to a person. Contractors must have an agency policy regarding abuse and neglect.

Abuse Reporting

Abuse Compliance and Monitoring

Texas Family Code, Chapter 261, requires suspected abuse or neglect of a child to be reported. Human Resources Chapter 48 requires suspected abuse, neglect, or exploitation of an elderly person, a person with a disability, or an individual receiving services from certain home and community-based providers to be reported.

Contractors are required to develop policies and procedures that comply with the child abuse reporting guidelines and requirements set forth in Chapter 261.

Policy

Contractors must develop an internal policy specific to address:

- how child abuse reporting requirements will be implemented throughout their agency;
- how abuse of persons outlined in Human Resource Chapter 48 will be implemented throughout their agency;
- how staff will be trained; and
- how internal monitoring will be done to ensure timely reporting.

To verify compliance; the contractor must:

- have an internal policy which details how the contractor will determine, document, report, and track instances of abuse, sexual or non-sexual, for all child/minor clients under the age of 18 in compliance with the Texas Family Code, Chapter 261;

- ◊ Note: Pursuant to TFC Sec. 101.003: "Child" or "minor" means a person under 18 years of age who is not and has not been married or who has not had the disabilities of minority removed for general purposes.
- have an internal policy which details how the contractor will determine, document, report, and track instances of abuse for clients outlined in Human Resources Chapter 48;
- follow their internal policy; and
- document staff training on abuse reporting requirements and procedures.

References for child abuse reporting policy development Child Abuse Reporting Requirements for contractors includes links to policies, child abuse reporting form, and statutory references. Available at: https://www.dfps.state.tx.us/contact_us/report_abuse.asp.

Human Trafficking

Contractors must comply with the state and federal anti-trafficking laws, including the Trafficking Victims Protection Act of 2000 (22 USC § 7101, et seq.) and Title 3 Occupations Code Chapter 116 (Training Course on Human Trafficking Prevention).

Contractors must have a written policy on human trafficking which includes the provision of annual staff training.

References for human trafficking policy development include:

- Human trafficking into and within the United States: A review of the literature on human trafficking in the US for the US Department of Health & Human Services.
- Polaris Project website: Contains links to victim and survivor support and other resources for healthcare providers and victims.
- Polaris Project - Recognize the signs: Provides lists of common identifiable features of human trafficking victims in multiple settings.
- Rescue and Restore Campaign by the US Dept of Health and Human Services. Contains multiple resources for healthcare providers, social service personnel, and law enforcement for identifying and aiding trafficking victims; includes PowerPoint presentations for training purposes.
- Texas Human Trafficking Resource Center is a statewide directory connecting Health and Human Services staff, healthcare providers, stakeholders and potential victims of human trafficking to local, state and national resources to identify and help people affected by human trafficking.

Domestic and Intimate Partner Violence (IPV)

Intimate partner violence (IPV) describes physical, sexual, or psychological harm by a current or former partner or spouse. IPV may also be referred to as domestic violence or family violence. Per Texas Human Resources Code Chapter 51, family violence may also include emotional harm and a threat of harm. This type of violence can occur among heterosexual or same-sex couples and does not require sexual intimacy.

Contractors must have a written policy related to assessment and prevention of domestic and intimate partner violence, including the provision of annual staff training.

CHAPTER 3: CLIENT RIGHTS

Confidentiality

All contracting agencies must be in compliance with the U.S. Health Insurance Portability and Accountability Act of 1996 (HIPAA) established standards for protection of privacy.

A contractor must document the individual's preferred method of follow-up for clinic services (cell phone, email, work phone) and the individual's preferred language. Contractor must verbally assure each individual the right to confidentiality. Contractors must comply with adult and child abuse and neglect reporting laws in Texas. A health-care provider may not require consent for services from the spouse of a married client.

Contractors must ensure that all employees and volunteers receive training about client confidentiality during orientation and be made aware that violation of the law in regard to confidentiality may result in civil damages and criminal penalties. A health-care provider's staff (paid and unpaid) must be informed during orientation of the importance of keeping client information confidential. All employees, volunteers, subcontractors, board members and/or advisory board members must sign a confidentiality statement during orientation.

The client's preferred method of follow-up to clinic services (cell phone, email, work phone, and/or text) and preferred language must be documented in the client's record. Clients must receive verbal assurance of confidentiality, an explanation of what confidentiality means, and any applicable exceptions such as abuse reporting.

Minors and Confidentiality

Except as permitted by law, a provider is legally required to maintain the confidentiality of care provided to a minor without the documented consent of the minor's legally authorized representative, or the minor when allowed by law. Confidential care does not apply when the law requires parental notification or consent or when the law requires the provider to report health information, such as in the cases of contagious disease or abuse. While confidentiality is implicit in maintaining a person's privacy, confidentiality between provider and a person is not an absolute right.

The HIPAA privacy rule requires a covered entity to treat a "personal representative" the same as the person with respect to uses and disclosures of the

person's protected health information. In most cases, parents are the personal representatives for their minor children, and they can exercise individual rights, such as access to medical records, on behalf of their minor children. (See: Title 45 of the Code of Federal Regulations, Part 164).

Non-Discrimination

HHSC contractors must comply with state and federal anti-discrimination laws. These laws are contained in the Health and Human Services Commission (HHSC) Uniform Terms and Conditions – Grant Version 2.15, which include:

- Title VI of the Civil Rights Act of 1964 (42 U.S.C. §2000d et seq.);
- Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. §794);
- Americans with Disabilities Act of 1990 (42 U.S.C. §12101 et seq.);
- Age Discrimination Act of 1975 (42 U.S.C. §§6101-6107); and
- Title IX of the Education Amendments of 1972 (20 U.S.C. §§1681 et seq.).

Additionally, contractors must comply with Article IX, Section 9.21 (a-f) Civil Rights, the HHSC Special Conditions Version 1.1, Article V, Section 5.06 Services, and Information for Persons with Limited English Proficiency, which are part of a contractor's contract with the State.

It is highly recommended that contractors comply with Texas Government Code, § 2054.457, Access to Electronic and Information Resources.

More information about non-discrimination laws and regulations can be found on the HHSC Civil Rights website and at the HHSC Civil Right Office, Requirements for Contractors website.

Contract Terms and Conditions

To ensure compliance with non-discrimination laws, regulations, and policies, contractors must:

- sign a written assurance to comply with applicable federal and state non-discrimination laws and regulations;
- have a written policy that states the agency does not discriminate based on race, color, national origin, including limited English proficiency (LEP), sex, age, religion, disability, or sexual orientation;
- have a policy that addresses individual rights and responsibilities that is applicable to all individuals requesting services;

- have procedures for notifying the HHSC Civil Rights Office of any program or service-related discrimination allegation or complaint no more than ten (10) calendar days of the allegation or complaint;
- ensure that all contractor staff is trained in the contractor's non-discrimination policies, including policies for serving individuals with LEP and individuals with disabilities, and HHSC complaint procedures;
- notify all individuals who are applying for services of the contractor's non-discrimination policies and complaint procedures; and
- prominently display civil rights posters in common areas, including lobbies and waiting rooms, front reception desk, and locations where individuals apply for services; posters can be found on the Civil Rights Office website.

Questions concerning this section and civil rights matters can be directed to the HHSC Civil Rights Office.

Limited English Proficiency

To ensure compliance with civil rights requirements related to LEP, contractors must:

- take reasonable steps to ensure that people with LEP have meaningful access to its programs and services, and not require a person with LEP to use friends or family members as interpreters; however, a family member or friend may serve as a person's interpreter, if requested, and if the family member or friend does not compromise the effectiveness of the service or violate client confidentiality; and
- make people with language service needs, including persons with LEP and disabilities, aware that the contractor will provide an interpreter free of charge.

Former Military Service Members

Women and men who served in any branch of the United States Armed Forces, including Army, Navy, Marines, Air Force, Coast Guard, Reserves or National Guard, may be eligible for benefits and services under other HHSC programs. For more information, please visit the Texas Veterans Portal.

Termination of Services

Contractors have the right to terminate services to an individual if the client is disruptive, unruly, threatening, or uncooperative to the extent that the client

seriously impairs the contractor's ability to effectively and safely provide services or if the client's behavior jeopardizes his or her own safety, clinic staff, or others. A client has the right to appeal the denial, suspension, or termination of services.

Contractors must have a written policy related to termination of services.

Resolutions of Complaints

Contractors must ensure that clients can express concerns about care received and to further ensure that those complaints are handled in a consistent manner. Contractors' policy must explain the process clients may follow if they are not satisfied with the care received. If an aggrieved client requests a hearing, a contractor shall not terminate services to the client until a final decision is rendered by HHSC. Any complaint must be documented in the client's record.

Freedom of Choice

Clients have the right to choose healthcare providers and family planning methods, if applicable, without coercion or intimidation. Acceptance of healthcare services does not preclude eligibility for or receipt of any other service or assistance.

Research (Human Subject Clearance)

A contractor that wishes to participate in any proposed research that would involve the use of Women's Health Programs clients as subjects, the use of clients' records, or any data collection from clients, must obtain prior approval from their own internal Institutional Review Board (IRB) and HHSC. For information about the process, contractors should contact the Department of State Health Services' (DSHS) IRB at InstitutionalReviewBoard@dshs.texas.gov. The IRB will review the materials and approve or deny the application.

The contractor must have a policy in place that indicates that prior approval will be obtained from HHSC, prior to instituting any research activities. The contractor must also ensure that all staff is made aware of this policy through staff training. Documentation of training on this topic must be maintained. Federal BCCS funds may not be used for research.

CHAPTER 4: CONSENT

General Consent Contractors must obtain the client's written, informed, voluntary general consent to receive services prior to receiving any clinical services pursuant to applicable state and federal law. A general informed consent explains the types of services provided and how client information may be shared with other entities for reimbursement or reporting purposes. If there is a period of time of three years or more during which a person does not receive services, a new general consent must be signed prior to reinitiating delivery of services.

Consent information must be effectively communicated to every client in a manner that is understandable. This communication must allow the client to participate, make sound decisions regarding their own medical care, and address any disabilities that impair communication (in compliance with Limited English Proficiency regulations). Only the client receiving services may give consent. For situations when the client is legally unable to consent, in which case a parent (i.e. in the case of an unemancipated minor) or court-appointed legal guardian must consent on their behalf. Consent must never be obtained in a manner that could be perceived as coercive.

In addition, as described below, the contractor must obtain informed consent of the client for procedures as required by the Texas Medical Disclosure Panel.

HHSC contractors should consult a qualified attorney to determine the appropriateness of all consent forms used by their health care agency.

Program-Specific Consent

Clients entering BCCS for services must also sign consent authorizing the contractor to enter or view client protected health information in the statewide Med-IT database. If this statement is not included in the general consent, an additional consent must be developed for the client to sign and include with the general consent in the patient health record.

Clients receiving patient navigation services for clinical abnormalities must sign a consent to ongoing assessment for needs and care coordination planning.

Procedure-Specific Informed Consents

Sterilization Procedures:

There are two consent forms required for sterilization procedures:

- Sterilization Consent Form, and
- Texas Medical Disclosure Panel Consent.

The Sterilization Consent Form

The Sterilization Consent Form is necessary for both abdominal and trans-cervical sterilization procedures in women and vasectomy in men. It is published in the Texas Medicaid Provider Procedures Manual (TMPPM) and is the only acceptable consent form for sterilizations funded by FPP and HTW.

An electronic copy of the Sterilization Consent Forms (in English and Spanish) may be found on the TMHP website. It is important that contractors use the most recent Sterilization Consent Form available. Additionally, it is the contractor's responsibility to ensure that the form is complete and accurate prior to submission to TMHP.

In brief, the individual to be sterilized must:

- be at least **21 years old** at the time the consent is obtained;
- be mentally competent;
- voluntarily give his or her informed consent;
- sign the consent form **at least 30 days but not more than 180 days prior** to the sterilization procedure*.

Additionally, the individual to be sterilized may choose a witness to be present when the consent is obtained.

**An individual may consent to be sterilized at the time of premature delivery or emergency abdominal surgery, if at least 72 hours have passed after the individual gave informed consent to sterilization. In the case of premature delivery, the informed consent must have been given at least 30 days before the expected date of delivery.*

The consent form must be signed and dated by the:

- person to be sterilized;
- interpreter, if one is provided;
- person who obtains the consent; and
- physician who will perform the sterilization procedure.

Informed consent may **not** be obtained while the individual to be sterilized is:

- in labor or in the process of delivering an infant or infants;
- seeking to obtain or obtaining an abortion; or

- is under the influence of alcohol or other substances that affect the individual's state of awareness.

Texas Medical Disclosure Panel Consent

The Texas Medical Disclosure Panel (TMDP) was established by the Texas Legislature to 1) determine which risks and hazards related to medical care and surgical procedures must be disclosed by health care providers or physicians to their patients or persons authorized to consent for their patients, and 2) establish the general form and substance of such disclosure. TMDP has developed a list of procedures that require full and specific disclosure (List A) for certain procedures. More information about the TMDP can be found in the TMDP or the Civil Practice and Remedies Code, Chapter 74.102.

For all other procedures not on List A, the physician must disclose, through a procedure-specific consent, all risks that a reasonable patient would want to know. This includes all risks that are inherent to the procedure (one which exists in and is inseparable from the procedure itself) and that are material (could influence a reasonable person in making a decision whether or not to consent to the procedure).

Contractors that directly perform tubal sterilization and/or vasectomy (both List A procedures), must also complete the TMDP Disclosure and Consent Form. This consent is in addition to the Sterilization Consent Form noted on the previous page.

The required disclosures for tubal sterilization are:

- injury to the bowel and/or bladder;
- sterility;
- failure to obtain fertility (if applicable);
- failure to obtain sterility (if applicable); and
- loss of ovarian functions or hormone production from ovary(ies).

The required disclosures for vasectomy are:

- loss of testicle; and
- failure to produce permanent sterility.

Consent for Services to Minors

Minors age 17 and younger are required to obtain consent from a parent, managing conservator, or court appointed guardian before receiving HTW services as required

by Texas Family Code, Chapter 151, and may consent to their own services only as authorized by Texas Family Code, Chapter 32, or by federal law or regulations. A parent or legal guardian must apply on the behalf of a minor age 15-17 for HTW services and provide documentation as required by HHSC. FPP contractors must have proof of a parent's or guardian's consent prior to providing FPP services to a minor. Proof of consent must be included in the minor client's medical record.

Minors may consent to HIV/STD testing and treatment for an STD. Parental consent is **not** required for minors to receive pregnancy testing, HIV/STD testing, or treatment for a STD.

For information on health services and consent requirements for minors see: Adolescent Health – A Guide for Providers and The Texas Family Code, Chapter 32, part of which is outlined below.

Texas Family Code Chapter 32 Sec. 32.003. CONSENT TO TREATMENT BY CHILD: There are instances in which a child may consent to medical, dental, psychological, and surgical treatment for the child by a licensed physician or dentist if the child:

1. is on active duty with the armed services of the United States of America;
2. is:
    a. 16 years of age or older and resides separate and apart from the child's parents, managing conservator, or guardian, with or without the consent of the parents, managing conservator, or guardian and regardless of the duration of the residence; and
    b. managing the child's own financial affairs, regardless of the source of the income;
3. consents to the diagnosis and treatment of an infectious, contagious, or communicable disease that is required by law or a rule to be reported by the licensed physician or dentist to a local health officer or the Texas Department of Health, including all diseases within the scope of Section 81.041, Health and Safety Code;
4. is unmarried and pregnant and consents to hospital, medical, or surgical treatment, other than abortion, related to the pregnancy;
5. consents to examination and treatment for drug or chemical addiction, drug or chemical dependency, or any other condition directly related to drug or chemical use;

6. is unmarried, is the parent of a child, and has actual custody of his or her child and consents to medical, dental, psychological, or surgical treatment for the child; or
7. is serving a term of confinement in a facility operated by or under contract with the Texas Department of Criminal Justice, unless the treatment would constitute a prohibited practice under Section 164.052(a)(19), Occupations Code.

Consent for HIV Tests

Contractors must comply with Texas Health and Safety Code §81.105 and §81.106 as follows:

§81.105. INFORMED CONSENT

- Except as otherwise provided by law, a person may not perform a test designed to identify HIV or its antigen or antibody without first obtaining the informed consent of the person to be tested.
- Consent need not be written if there is documentation in the medical record that the test has been explained and the consent has been obtained.

§81.106. GENERAL CONSENT

- A person who has signed a general consent form for the performance of medical tests or procedures is not required to also sign or be presented with a specific consent form relating to medical tests or procedures to determine HIV infection, antibodies to HIV, or infection with any other probable causative agent of AIDS that will be performed on the person during the time in which the general consent form is in effect.

Except as otherwise provided by this chapter, the result of a test or procedure to determine HIV infection, antibodies to HIV, or infection with any probable causative agent of AIDS performed under the authorization of a general consent form in accordance with this section may be used only for diagnostic or other purposes directly related to medical treatment.

CHAPTER 5: CLIENT RECORD MANAGEMENT

Contractors must have an organized and secure client record system. The contractor must ensure that the record is organized, readily accessible, and available to the client upon request with a signed release of information. Records must be kept confidential and secure, as follows:

- safeguarded against loss or use by unauthorized persons;
- secured by lock when not in use and inaccessible to unauthorized persons; and
- maintained in a secure environment in the facility, as well as during transfer between clinics and in between home and office visits.

Written consent of the client is required for the release of personally identifiable information, except as may be necessary to provide services to the client or as required by law, with appropriate safeguards for confidentiality. If the client is 17 years of age or younger, the client's parent, managing conservator, or guardian, as authorized by Chapter 32 or Chapter 151 of the Texas Family Code, or by federal law or regulations, must authorize the release. HIV information must be handled according to law.

When information is requested, contractors should release only the specific information requested. Information collected for reporting purposes may be disclosed only in summary, statistical, or other form that does not identify particular clients. Upon request, clients transferring to other providers must be provided with a copy or summary of their record to expedite continuity of care. Electronic records are acceptable as medical records.

Contractors, providers, subrecipients, and subcontractors must maintain for the time period specified by HHSC all records pertaining to client services, contracts, and payments. Contractors must follow contract provisions, maintain medical records for at least seven years after the close of the contract, and follow the retention standards of the appropriate licensing entity. All records relating to services must be accessible for examination at any reasonable time to representatives of HHSC and as required by law.

CHAPTER 6: PERSONNEL

Contractors must develop and maintain personnel policies and procedures to ensure that all staff are hired, trained, and evaluated appropriately for their job position. Personnel policies and procedures must include:

- job descriptions;
- a written orientation plan for new staff to include skills evaluation and/or competencies appropriate for the position; and
- a performance evaluation process for all staff.

Job descriptions, including those for contracted personnel, must specify required qualifications and licensure. All staff must be appropriately identified with a name badge.

Contractors must show evidence that employees meet all required qualifications and are provided annual training. Job evaluations should include observation of staff/client interactions during clinical, counseling, and educational services.

Contractors shall establish safeguards to prohibit employees from using their positions for a purpose that constitutes or presents the appearance of personal or organizational conflict of interest or personal gain. All employees and board members must complete a conflict of interest statement during orientation. All medical care must be provided under the supervision, direction, and responsibility of a qualified Medical Director. The Medical Director must be a licensed Texas physician.

Contractors must have a documented plan for organized staff development. There must be an assessment of:

- training needs;
- quality assurance indicators; and
- changing regulations/requirements.

Staff development must include orientation and in-service training for all personnel and volunteers. Non-profit entities must provide orientation for board members and government entities must provide orientation for their advisory committees. Employee orientation and continuing education must be documented in agency personnel files.

CHAPTER 7: FACILITIES

Facilities and Equipment

HHSC contractors are required to maintain a safe environment at all times. Contractors must have written policies and procedures that address the handling of hazardous materials, fire safety, and medical equipment.

Hazardous Materials

Contractors must have written policies and procedures that address:

- handling, storing, and disposing of hazardous materials and waste, according to applicable laws and regulations;
- handling, storing, and disposing of chemical and infectious waste, including sharps; and
- an orientation and education program for personnel who manage or have contact with hazardous materials and waste.

Fire Safety

Contractors must have a written fire safety policy that includes a schedule for testing and maintenance of fire safety equipment. Evacuation plans for the premises must be clearly posted and visible to all staff and clients.

Medical Equipment

Contractors must have a written policy and maintain documentation of the maintenance, testing, and inspection of medical equipment including an Automated External Defibrillator (AED). Documentation must include:

- Assessments of the clinical and physical risks of equipment through inspection, testing, and maintenance;
- Reports of any equipment management problems, failures and use errors;
- An orientation and education program for personnel who use medical equipment; and
- Manufacturer recommendations for care and use of medical equipment.

Radiology Equipment and Standards

All facilities providing radiology services must:

- possess a current Certificate of Registration from the DSHS Radiation Control Program;
- have operating and safety procedures as required by Title 25, Texas Administrative Code Chapter 289, Texas Regulations for Control of Radiation; and
- post NOTICE TO EMPLOYEES, Texas Regulations for Control of Radiation.

For information on x-ray machine registration, see the DSHS Radiation Control Program.

Smoking Ban

Contractors must have written policies that prohibit smoking in any portion of their indoor facilities. If a contractor subcontracts with another entity for the provision of health services, the subcontractor must comply with this policy.

Disaster Response Plan

Contractors must have written and oral plans that address how staff are to respond to emergency situations (i.e., fires, flooding, power outage, bomb threats, etc.). The disaster plan must identify the procedures and processes that will be initiated during a disaster and the staff (position/s) responsible for each activity. A disaster response plan must be in writing, formally communicated to staff, and kept in the workplace available to employees for review. For an employer with ten or fewer employees the plan may be communicated orally to employees.

For additional resources on facilities and equipment, see the Occupational Safety and Health Administration website.

CHAPTER 8: QUALITY MANAGEMENT

Quality Management Contractors must use internal Quality Assurance/Quality Improvement (QA/QI) systems and processes to monitor services. Contractors must have the ability to meet the management standards prescribed in 2 CFR Part 200.

Contractors should integrate Quality Management (QM) concepts and methodologies into the structure of the organization and day-to-day operations. QM programs can vary in structure and organization and will be most effective if they are individualized to meet the needs of a specific agency, services, and the populations served.

Contractors are expected to develop quality processes based on four core QM principles that focus on:

- the client;
- systems and processes;
- measurements; and
- teamwork.

Contractors must have a QM program individualized to their organizational structure and based on the services provided. The goals of the quality management program should ensure availability and accessibility of services, quality and continuity of care.

A QM program must be developed and implemented that provides for ongoing evaluation of services. Contractors should have a comprehensive plan for the internal review, measurement, and evaluation of services, the analysis of monitoring data, and the development of strategies for improvement and sustainability.

Contractors who subcontract for the provision of services must also address how quality will be evaluated and how compliance with HHSC policies and basic standards will be assessed with the subcontracting entities.

The QM Committee, whose membership consists of key leadership of the organization, including the Executive Director/CEO and the Medical Director, and other appropriate staff where applicable, annually reviews and approves the quality work plan for the organization.

Quality Management Committee

The Quality Management Committee must meet at least quarterly to:

- receive reports of monitoring activities;
- make decisions based on the analysis of data collected;
- determine quality improvement actions to be implemented; and
- reassess outcomes and goal achievement.

Minutes of the discussion and actions taken by the Committee and a list of the attendees must be maintained.

Comprehensive Quality Work Plan

The comprehensive quality work plan at a minimum must:

- include clinical and administrative standards by which services will be monitored;
  include process for credentialing and peer review of clinicians;
- identify those responsible for implementing, monitoring, evaluating and reporting;
- establish timelines for quality monitoring activities;
- identify tools/forms to be utilized; and
- outline reporting to the Quality Management Committee.

Quality Assurance Activities

Although each organization's quality assurance program is unique, the following activities must be undertaken by all agencies providing client services:

- on-going eligibility, billing, and clinical record reviews to ensure compliance with program requirements and clinical standards of care;
- utilization review;
- tracking and reporting of adverse outcomes;
- client satisfaction surveys;
- annual review of facilities to maintain a safe environment, including an emergency safety plan;
- annual review of policies, clinical protocols and standing delegation orders (SDOs) to ensure they are current; and
- up to date performance evaluations that include primary license verification, Drug Enforcement Administration, and immunization status.

Subrecipient Quality and Compliance

Contractors who subcontract with subrecipients for the provision of services must also address how quality will be evaluated and how compliance with policies and basic standards will be assessed with the subrecipient including:

- annual license and certification verification (primary source verification);
- clinical record review;
- billing and eligibility review;
- utilization review;
- facility on-site review;
- annual client satisfaction evaluation process; and
- child abuse training and reporting.

Data from these activities must be presented to the QM Committee. Plans to improve quality should result from the data analysis and reports considered by the committee and should be documented.

Clinical Quality Assurance

Ambulatory Surgical Centers

Ambulatory Surgical Centers that provide services must be CMS certified, state licensed, and Joint Commission accredited, as applicable. See the directory of licensed ambulatory surgical centers.

Mammography Quality Assurance

All contractors and subcontractors providing mammography services must:

- Possess a current Certification of Mammography Systems from DSHS Regulatory Licensing Unit, Mammography Certification Program (each mammography unit must be fully accredited or undergoing accreditation); and
- Possess a current mammography facility certificate from the appropriate agency certifying compliance with the U.S. Food and Drug Administration Mammography Quality Standards, at 21 CFR Part 900.

The Mammography Radiation Control Program may be contacted or certification questions and information on inspection results, escalated enforcement, or "cease and desist" status

Cytology Quality Assurance

Contractors and subcontracting entities for screening and diagnostic cytology services must have current documentation that the agency meets all quality assurance standards required by the Women's Health Programs as established under state and federal laws.

All cytology laboratories providing services to contractors/subcontractors must:

- possess a current, unrevoked, and unsuspended registration certificate issued by the U.S. Department of Health and Human Services under the terms of the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88) (42 U.S.C. §263a);
- use the 2001 Bethesda System for Reporting Cervical/Vaginal Cytological Diagnoses; and
- the lab must have a mechanism for expedited notification of Pap tests which are CIN III or greater, such that the clinic is notified no later than the next business day after the case is signed out.

HPV Quality Assurance

Contractors must assure the following for all HPV tests:

- must be for high-risk oncogenic types; and
- must be FDA approved and clinically validated.

CHAPTER 9: PHARMACY

Class D Pharmacy

In accordance with national best practices to achieve the goal of reducing unintended pregnancy, HHSC expects that FPP clients will leave family planning clinic appointments with their desired contraceptive method. To facilitate immediate client access to contraceptive services, contractors must provide certain pharmaceutical services (including contraceptive methods and related medications) to family planning clients at each FPP-funded clinic site.

All FPP contractors, at minimum, must provide the following contraceptive methods at each clinic site:

- injectable hormonal contraceptives;
- barrier methods and spermicides; and
- counseling and education on sexual abstinence.

Each FPP clinic site must maintain an adequate supply and variety of drugs and devices on-site to effectively manage the contraceptive needs of its patients.

Contractors must have a minimum Class D pharmacy license at each FPP clinic site or be able to provide immediate client access to contraceptive methods and related medications through a written and signed vendor agreement with a pharmacy or pharmacies of the contractor's choice.

Pharmacies must be operated in accordance with federal and state laws relating to security and record-keeping for drugs and devices. The inventory, supply, and provision of pharmaceuticals must be conducted in accordance with state pharmacy laws and professional practice regulations.

The contractor must ensure all contraceptive methods and related medications approved for reimbursement by the FPP are made available at no additional charge to the client. The participating pharmacy or pharmacies must not charge the client or incur additional costs (such as a co-payment) to obtain medications.

If certain contraceptives and related medications will not be provided on-site, the contractor must have a written and signed vendor agreement with a pharmacy or pharmacies, which includes the purpose of the cooperation and details coordination between the contractor and the pharmacy or pharmacies to provide the following medications:

- non-clinician administered hormonal contraceptive methods
  - oral contraceptives;
  - transdermal hormonal contraceptives (patch) or vaginal hormonal contraceptives (ring);
- anti-infectives for the treatment of STIs and other infections.

The pharmacy or pharmacies must be located within a reasonable distance to participating clients.

The contractor must have a written policy that ensures clients can obtain prescribed medication refills from the cooperating pharmacy or pharmacies without an additional clinic visit (unless medically indicated/necessary).

Vendor Drug Program

HTW uses the Vendor Drug Program (VDP), which provides statewide access to covered outpatient drugs in an efficient and cost-effective manner. HTW clients may receive approved medications from an associated pharmacy at no cost to the client by providing a HTW benefits card. For further information on the VDP, what drug benefits are covered by HTW, and to locate local pharmacies visit: https://www.txvendordrug.com/providers.

CHAPTER 10: Reimbursement

Reimbursement for Services

Contractors may seek reimbursement for project costs using one or two methods:

- Contractors may submit monthly vouchers for expenses outlined in a cost reimbursement budget approved by HHSC, as required for the cost reimbursement method; and/or
- Contractors may be reimbursed using the fee-for-service reimbursement method by submitting claims to TMHP or Med-IT for services rendered.

Contractors' FPP cost reimbursement award may not exceed 25 percent of their total FPP award. Contractors may designate up to 100 percent of their total FPP award on a fee-for-services basis.

Contractors' HTW cost reimbursement award may not exceed 25 percent of their expected HTW fee-for-service payments for the contract year.

Cost Reimbursement

Cost reimbursement funds should not be used for the provision of direct client services paid through fee-for-service. Costs may be assessed against any of the following categories the contractor identifies during their budget development process, including associated costs for:

1. Assisting eligible women with enrollment into the WHP program;
2. Direct clinical care for women deemed presumptively eligible for the HTW fee-for-service program and ultimately denied eligibility;
3. Staff development and training related to HTW and/or FPP program service delivery;
4. Client and community based educational activities related to the HTW and/or FPP; and
5. Purchasing LARC devices such as IUDs and contraceptive implants.

Costs may be assessed against any of the following categories the contractor identifies during their budget development process:

a. personnel,
b. fringe benefits,
c. travel,
d. equipment and supplies,

e. contractual,
f. other, and
g. indirect costs.

NOTE: Indirect costs are costs incurred for a common or joint purpose benefiting more than one project or cost objective of respondent's organization and not readily identified with a particular project or cost objective. Typical examples of indirect costs may include general administration and general expenses such as salaries and expenses of executive officers, personnel administration and accounting; depreciation or use allowances on buildings and equipment; and costs of operating and maintaining facilities. Contractors are required to have an indirect cost rate to receive indirect reimbursements.

LARC devices such as IUDs and contraceptive implants may be purchased in bulk using cost reimbursement dollars and should be accounted for in the "supplies" section of a contractor's budget. The contractor will bill TMHP for the insertion of the LARC device only when issued to a patient.

Reimbursement is requested by using a purchase voucher and supporting schedule. To request reimbursement for the cost reimbursement contract, the following forms must be submitted by the last business day of the month following the month in which expenses were incurred or services provided:

- State of Texas HHSC Purchase Voucher;
- Supporting Schedule for HHSC Purchase Voucher. (Form B-13)

The following forms must be submitted within **45 days following the end of the contract term**:

- Final State of Texas HHSC Purchase Voucher;
- Supporting Schedule for HHSC Purchase Voucher. (Form B-13).

No more than five percent of the cost reimbursement payments will be received under this contract for expenses related to performing administrative functions derived from subcontracting the terms of the contract. Administrative functions include, but are not limited to, the contractor's personnel costs for provision of oversight and technical assistance related to contracting with a subcontractor, monitoring subcontractor performance, and all other related general and administrative expenses for administration of the subcontract, such as related fringe, rent, and office supplies.

HTW Claims Pending Eligibility Determination

Contractors must hold claims up to 45 calendar days for clients who were screened as presumptively eligible and have applied to HTW. If a client's HTW eligibility has not been determined after 45 calendar days, the contractor may bill the service to the cost reimbursement program if the client has a current eligibility form on file. If the contractor files a cost reimbursement program claim for a potentially HTW and/or FPP eligible client before the end of the 45-day waiting period, the contractor must include a copy of the client's HTW and/or FPP denial letter in the client record before filing the claim or encounter.

IUD and Contraceptive Implant Complications

Contractors may request reimbursement for costs associated with patient complications related to IUD or Contraceptive Implant insertions or removals. Contractors may be reimbursed for approved charges up to $1,000 per occurrence. To request reimbursement contractors should provide the HHSC HTW program with the following information:

- A copy of the R&S report showing that a IUD or Contraceptive Implant insertion or removal procedure was performed on the client in question;
- A narrative summary detailing the procedure performed and any related complications;
- All surgical and progress notes for the client related to the complication of the IUD or Contraceptive Implant insertion or removal procedure; and
- A completed CMS 1500 Claim Form or a 2017 Claim Form detailing the procedures for which the contractor is seeking reimbursement (list all procedures related to the complication even if they are not typically reimbursable under the HHSC HTW program).

Fee-for-Service Reimbursement

The fee-for-service component of funding pays for direct medical services on a fee-for-service basis. Up to 100 percent of the budget may be reimbursed on a fee-for-service basis. Each contracting agency is responsible for determining an individual's eligibility for clinical services. The WHP reimburses contractors on a fee-for-service basis for services and supplies that have been provided to eligible individuals. Contractors must continue to provide services to established individuals and to submit and appeal claims for individual services even after the contract funding limit has been met.

FPP and HTW contractors are required to submit claims for all HHSC services to TMHP using the 2017 Claim Form, which is available from the TMHP website. The TMPPM provides detailed instructions of how to complete the form, including required and optional fields. FPP and HTW contractors may also submit professional claims electronically using a modified CMS-1500 electronic claim form. BCCS contractors are required to file claims electronically through the Med-IT system.

HHSC claims or appeals must be filed within certain timeframes:

- Initial claims submission: Submitted within 95 days of the date of service on the claim or date of any third-party insurance explanation of benefit (EOB). If the 95th day falls on a weekend or holiday, the filing deadline is extended until the next business day.
- Appeals: Submitted within 120 days of the date on the R&S Report on which the claim reaches a finalized status. If the 120th day falls on a weekend or holiday, the filing deadline is extended until the next business day. If the claim is denied for late filing due to the initial submission deadline, documentation of timely filing must be submitted along with the claim appeal. Refer to the TMPPM for further information.
- All claims and appeals must be submitted and processed within 60 days after the end of the contract period.
- All claims must continue to be billed and denied claims appealed even after the contract funding limit has been met.

HHSC contractors may contact the TMHP Contact Center from 7:00 a.m. to 7:00 p.m. (CST), Monday through Friday at 800-925-9126 for questions about claims and payment status or Contact Med-IT (med-ithelpdesk@hhsc.state.tx.us).

Reimbursable Codes

Fee-for-service reimbursement is limited to a prescribed set of procedure codes approved by HHSC.

Contractors may submit claims for individuals' office visits that reflect different levels of service for new and established individuals. A new individual is defined as one who has not received clinical services at the contractor's clinic(s) during the previous three years. The level of services, which determines the procedure code to be billed for that individual visit, is indicated by a combination of factors such as the complexity of the problem addressed, and the time spent with the individual by clinic providers. The American Medical Association (AMA) publishes materials

related to Current Procedural Terminology (CPT) ® coding that include guidance on office visit codes (Evaluation and Management Services – E/M).

Medroxyprogesterone Acetate Injection

Providers may not bill a lower complexity office visit code (99211/99212) when the primary purpose is for the individual to receive an injection of Medroxyprogesterone acetate (Depo-Provera/DMPA/depo) injection. Rather, contractors should bill the injection fee (96372) with the Depo-Provera contraceptive method (J1050).

Electronic Claims Submission

All HHSC WHP contractors are strongly encouraged to submit claims electronically. For FPP and HTW claims, TMHP offers specifications for electronic claims formats. These specifications are available from the TMHP Provider Portal and relate the paper claim instruction to the electronic format. Contractors may use their own claims filing system, vendor software, or TexMedConnect (a free Web-based claims submission tool available through the TMHP website) for submission of electronic claims. For more information concerning electronic claims submission, contractors may contact the TMHP Electronic Data Interchange (EDI) Help Desk at 512-514-4150 or 888-863-3638. Additional information may be found on the TMHP website. For BCCS, claims are entered into Med-IT. Questions may be sent to the Med-IT Help desk (med-ithelpdesk@hhsc.state.tx.us).

SECTION III – BREAST AND CERVICAL CANCER SERVICES PROGRAM POLICIES

CHAPTER 1: BCCS CONTRACTOR RESPONSIBILITIES

Contractors shall provide and/or assure the provision of breast and/or cervical cancer screening, diagnostic and support services including tracking, follow-up, patient navigation, and individual client education services. Although BCCS allows the provision of diagnostic services, contractors must ensure that program focus supports cancer screening, consistent with funding intent.

Contractor requirements also include: program management, eligibility determination, initiation of or referral to treatment if clinically indicated, quality management, professional development, recruitment including public education and outreach and data collection, including tracking and follow-up. Collectively, these components will ensure the achievement of performance measures.

Contractors are responsible for the coordination of a client's services from screening through diagnosis, if clinically warranted. Contractors who have expended their awarded funds shall continue to serve their existing BCCS eligible clients who are currently in the process of an approved care plan. Contractors shall ensure that existing clients receive services from qualified breast and cervical cancer providers to continue client care.

All contractors must have an established referral relationship and sub-contract with a qualified provider of each service that the contractor does not provide. **Duplication of BCCS services by multiple contractors will not be reimbursed. Contractors should have procedures in place to verify clients are not receiving services with another BCCS contractor prior to services being rendered. NBCCEDP funds cannot be used to cover services covered by another public health program or private coverage (42 U.S.C. § 300m(d)).**

Program Management – The purpose of program management is to maximize available resources to implement and maintain BCCS components according to

BCCS policies and procedures. Contractors are required to coordinate and administer program activities with supportive management systems.

Eligibility – Contractors are required to determine BCCS program eligibility of every client at enrollment and annually thereafter. Insurance status should be reassessed at each client visit.

Quality Management – Contractors are expected to ensure the quality of services by monitoring performance and identifying opportunities for improvement. Contractors must have policies and procedures to ensure healthcare providers follow evidence-based clinical guidelines and provide clinical services consistent with current nationally recognized standards of care.

Professional Development – Contractors are responsible for ensuring health care professionals provide BCCS services competently and with sensitivity to diverse patient cultures.

Recruitment – Contractors must establish and maintain outreach and inreach methods to recruit priority populations.

Data Collection – Contractors are required to comply with and utilize the web-based system Med-IT® to collect and process breast and cervical cancer data, including reports and billing in accordance with the business requirements of the program.

Partnerships – Contractors must establish and maintain partnerships with coalitions, community-based organizations and other HHSC agencies that further the goal of providing breast and cervical cancer services in the proposed service area.

CHAPTER 2: CLIENT ELIGIBILITY

Eligibility Guidelines

For an individual to receive BCCS services, three (3) general criteria must be met:

- gross household income at or below 200 percent of the adopted Federal Poverty Level (FPL);
- applicant is a Texas resident; and
- without access to programs/benefits providing the same services.

Other Eligibility Factors

Other eligibility factors include:

- undocumented applicants who meet the general eligibility criteria are program eligible;
- applicant must meet age-specific eligibility criteria for screening and diagnostic services;
- applicants may be dual-eligible for programs providing the same or similar services, such as Healthy Texas Women and/or Family Planning. In such cases, individual agencies should determine the best use of funds to meet client needs and maintain program requirements. However, clients with a primary need of cancer screening should be enrolled in BCCS.
- Applicants with access to preventive (screening) services whose coverage is insufficient for diagnostic workup are considered underinsured and may be enrolled for services.

Contractor Responsibilities

Contractors must develop an agency policy to determine BCCS eligibility. The policy shall be available during Monitoring visits and must address the following:

- documents that are acceptable for verifying household income at or below 200 percent FPL (income must be recorded in client record and Med-IT®);
- use of the HHSC BCCS Eligibility Application (Form 1065); or,
- use of a comparable paper or electronic screening and eligibility tool with required information. If a comparable eligibility screening tool is being used, it must be reviewed and approved by HHSC staff before use. Contractors must use the BCCS Eligibility Application until approval to use a comparable

form is received. Contractor must maintain/retain proof of approval and shall make the approval available during QA visits.

Contractor eligibility policy must also ensure that:

- client insurance status is assessed before service delivery;
- all clients are educated on and assessed for Marketplace (www.healthcare.gov) eligibility;
- general BCCS eligibility is determined prior to enrollment and annually thereafter;
- clients age 65 and over do not meet eligibility unless client is ineligible for or unable to pay premiums for Medicare Part B.

If a woman is eligible to receive Medicare benefits and is not enrolled in Medicare, she should be encouraged to enroll. Women enrolled in Medicare Part B are not eligible to receive services. Women who are not eligible to receive Medicare Part B and Medicare-eligible women who cannot pay the premium to enroll in Medicare Part B are eligible to receive services. If a client cannot afford the additional expense of Medicare Part B Premiums, Medicaid-sponsored Medical Savings Programs may pay Medicare premiums, deductibles, and coinsurance amounts for eligible Medicare beneficiaries. The Qualified Medicare Beneficiary (QMB) program, the Specified Low-Income Medicare Beneficiary (SLMB) program, the Qualified Individuals (QI-1), and the Qualified Disabled Working Individuals (QDWI) program are all called Medicare Savings Programs. More information about Medicare Savings Programs may be referenced at the following website: http://www.medicare.gov/.

Applying for Services

Screening and Eligibility Determination

Contractors must use the HHSC BCCS Eligibility Application (Form 1065). Another eligibility screening form substitute (e.g., in-house form, electronic/automated form, phone interview, etc.) that contains the required information for determining eligibility may be used if approved by the BCCS program.

The applicant is responsible for completing the HHSC BCCS Eligibility Application. If assistance is needed to complete the form, the contractor shall provide knowledgeable staff to assist.

Special circumstances may occur in the disclosure of information by the applicant, documentation of pertinent facts, or events surrounding the applicant's application for services must be documented on the HHSC BCCS Eligibility Application. Special

circumstances must also be documented in the Med-IT® Data System in the notes section of the enrollment screen.

Household

Establishing household size is an important step in the eligibility process. Assessment of income eligibility relies on an accurate count of household members.

One application may be completed for all household members being screened for eligibility. To expedite the process, it is acceptable to fill out the form once and photocopy the form for the number of household members needed. The household member's name listed under the household information in section III can be highlighted/circled to indicate the intended client record in which the form will be filed. Each BCCS eligible applicant, who is a legal adult, is required to sign and date the form. The signature and date of anyone assisting the applicant to complete the form is also required. The form is filed in the client record.

The contractor has discretion to document special circumstances in the calculation of household composition. Additionally, if a separate household group is established within the applicant's household based on the documentation gathered, document the basis used for determining separate households on the HHSC BCCS Eligibility Application.

Residency

To be eligible for BCCS, an individual must be physically present within the geographic boundaries of Texas (there is no requirement regarding the amount of time an individual must live in Texas to establish residency for the purposes of BCCS eligibility). The individual must:

- have the intent to remain within the state, whether permanently or for an indefinite period; and
- not claim residency in any other state or country.

Income

To be eligible for BCCS services, applicants must provide verification of **gross** (before taxes) household income at or below 200 percent FPL. If the applicant is unable to provide verification, income may be self-declared by the applicant. Documentation of why an applicant self-declared income must be in the client record and in the Med-IT® Data System.

Note: Applicants seeking Medicaid for Breast and Cervical Cancer (MBCC) may not self-declare income. This includes women who have been diagnosed with a qualifying cancer by BCCS contractors or other health care providers**.** Any applicant who will be assisted by a BCCS contractor to apply for MBCC must have verification of income documented in her client record and on the eligibility screen in Med-IT®.

Calculation of Applicant's Federal Poverty Level Percentage

1. Determine the applicant's **household** size.
2. Determine the applicant's **total monthly income** amount.
3. Divide the applicant's **total monthly income** amount by the **maximum monthly income** amount at 100 percent FPL, for the appropriate **household size**.
4. Multiply by 100 percent.

The maximum monthly income amounts by household size are based on the Department of Health and Human Services federal poverty guidelines. The guidelines are subject to change around the beginning of each calendar year.

Count income already received and any income the household expects to receive.

Count terminated income in the month it was received. Use actual income and do not use conversion factors if terminated income is less than a full month's income.

Income Deductions - Dependent care expenses and payments made by a member of the household group shall be deducted up to the allowable amount:

- Legally obligated child support payments;
- $200.00 per child per month for children under age 2;
- $175.00 per child per month for children age 2-17; and
- $175.00 per dependent adult with disabilities per month age 18 and over.

Monthly Income Calculation - When income is received in lump sums, at irregular intervals, or at longer intervals than monthly (i.e. contract labor, seasonal employment, lump sums, etc.), the total amount received will be divided over the period of time the income is expected to cover household expenses in order to determine a monthly income. Convert the amount using one of the following methods:

- weekly income is multiplied by 4.33;
- income received every two weeks is multiplied by 2.17;

- income received twice a month is multiplied by 2.0; and
- income received annually is divided by 12.

For seasonal income, count the total income for the months worked in the overall calculation of income.

The table below details sources of earned and unearned income that contribute to the calculation of gross household income as well as income that is exempt from being counted.

Types of Income	Countable	Exempt
Alimony*	✓	
Adoption Payments		✓
Cash Gifts and Contributions*	✓	
Child Support Payments*	✓	
Child's Earned Income		✓
Crime Victim's Compensation		✓
Disability Insurance Benefits*	✓	
Dividends, Interest, and Royalties*	✓	
Educational Assistance*		✓
Energy Assistance		✓
Foster Care Payment		✓
In-Kind Income*		✓
Job Training		✓
Loans (Non-educational)*	✓	

Lump-Sum Payments*	✓	✓
Military Pay*	✓	
Mineral Rights*	✓	
Pensions and Annuities*	✓	
Reimbursements*	✓	
RSDI /Social Security Payments*	✓	
Self-Employment Income*	✓	
SSDI*	✓	
SSI Payments		✓
TANF		✓
Unemployment Compensation*	✓	
Veteran's Administration*	✓	✓
Wages and Salaries, Commissions*	✓	
Worker's Compensation*	✓	

**Explanation of income provided below*

Alimony – Count support payment(s) to a divorced person by a former spouse.

Cash Gifts and Contributions – Count unless they are made by a private, non-profit organization on the basis of need; and total $300.00 or less per household in a federal fiscal quarter (January – March, April – June, July – September, October – December). If these contributions exceed $300.00 in a federal quarter, count the excess amount as income in the month received.

Exempt any cash contribution for common household expenses, such as food, rent, utilities, and items for home maintenance, if it is received from a non-certified household member who:

- lives in the home with the certified household member,
- shares household expenses with the certified household member, and
- does not have a landlord/tenant relationship.

Child Support Payments – Count income after subtracting the maximum dependent care deduction from the total monthly income the household receives.

Disability Insurance Payments/SSDI - Countable. Social Security Disability Insurance is a payroll tax-funded, federal insurance program of the Social Security Administration.

Dividends, Interest and Royalties – Countable. Exception: Exempt dividends from insurance policies as income. Count royalties, minus any amount deducted for production expenses and severance taxes.

Educational loans, grants – includes money received as scholarships by students for educational purposes. Count only that part actually used for current living costs.

In-Kind Income – Exempt. An in-kind contribution is any gain or benefit to a person that is not in the form of money/check payable directly to the household, such as clothing, public housing, or food.

Loans (Non-educational) – Count as income unless there is an understanding that the money will be repaid, and the person can reasonably explain how he/she will repay it.

Lump-Sum Payments – Count as income in the month received if the person receives it or expects to receive it more often than once a year. Exempt lump sums received once a year or less, unless specifically listed as income.

Military Pay- Count military pay and allowances for housing, food, base pay, and flight pay, minus pay withheld to fund education under the G.I. Bill.

Mineral Rights – Countable. A payment received from the excavation of minerals such as oil, natural gas, coal, gold, copper, iron, limestone, gypsum, sand, gravel, etc.

Pensions and Annuities – Countable. A pension is any benefit derived from former employment, such as retirement benefits or disability pensions.

Reimbursements – Countable, minus the actual expenses. Exempt a reimbursement for future expenses only if the household plans to use it as intended.

RSDI/Social Security Payments – Count the Retirement, Survivors, and Disability Insurance (RSDI) benefit amount including the deduction for the Medicare premium, minus any amount that is being recouped for a prior RSDI overpayment.

Self-Employment Income – Count total gross earned, minus the allowable costs of producing the self-employment income.

Terminated Employment – Count terminated income in the month received. Use actual income and do not use conversion factors if terminated income is less than a full month's income. Income is terminated if it will not be received in the next usual payment cycle.

Unemployment Compensation Payments – Count the gross benefit less any amount being recouped for a Unemployment Insurance Benefit overpayment.

VA Payments – Count only the gross Veterans Administration (VA) payment, minus any amount being recouped for a VA overpayment. Exempt VA special needs payments, such as annual clothing allowances or monthly payments for an attendant for disabled veterans.

Wages, Salaries, Tips and Commissions – Count the actual (not taxable) gross amount.

Worker's Compensation – Count the gross payment, minus any amount being recouped for a prior worker's compensation overpayment or paid for attorney's fees. NOTE: The Texas Workforce Commission (TWC) or a court sets the amount of the attorney's fee to be paid.

Adjunctive Eligibility

An applicant is considered adjunctively (automatically) **financially** eligible for BCCS services at an initial or renewal eligibility screening if she or a member of her household **is currently enrolled** in at least one of the programs listed below. An applicant must provide proof of active enrollment in the adjunctively eligible program. Acceptable eligibility verification documentation may include:

PROGRAM	ACCEPTED DOCUMENTATION
Children's Health Insurance Program (CHIP) Perinatal	CHIP Perinatal benefits card
Medicaid for Pregnant Women	"Your Texas Benefits" card (Medicaid card) *
Special Supplemental Nutrition Program for Women, Infants, and Children (WIC)	WIC verification of certification letter, printed WIC-approved shopping list or recent WIC purchase receipt with remaining balance
Supplemental Nutrition Assistance Program (SNAP)	SNAP eligibility letter
Temporary Assistance for Needy Families (TANF)	TANF verification of certification letter

*NOTE: Presentation of the "Your Texas Benefits" card does not completely verify current eligibility in the Medicaid for Pregnant Women program. To verify eligibility providers must call TMHP at 1-800-925-9126 or log on to TexMedConnect to check the member's Medicaid ID number (PCN).

If the applicant or the applicant's child (must be considered part of the household) is enrolled in the Children's Health Insurance Program (CHIP), she may be considered adjunctively eligible.

If the applicant's current enrollment status cannot be verified during the eligibility screening process, adjunctive eligibility would not be granted. Contractor would then determine eligibility according to usual protocols.

A copy of the accepted documentation must be kept in the client's record and available during QA reviews.

Date Eligibility Begins

Clients are eligible to start receiving services beginning with the date an application is completed and the client is determined eligible. Services rendered prior to the date the client is determined eligible will not be reimbursed.

Fees/Co-Payments

Clients shall not be charged administrative fees for items such as processing and/or transfer of medical records, copies of immunization records, etc.

Contractors are allowed to bill clients for services outside the scope of BCCS allowable services if the service is provided at the client's request and the client is made aware of his/her responsibility for paying the charges prior to services being rendered.

Continuation of Services

Contractors who have expended their awarded funds must continue to serve their existing eligible clients who are currently in the process of a care plan. It is allowable to obtain other funding to pay for these services (dependent on the funding source, this can be counted towards the match requirement.

Contractors who have expended their awarded funds are not required to enroll new clients. However, it is allowable to offer services at full-pay or on a sliding scale basis.

MED-IT® Data and Billing System

Before entering a woman into the Med-IT® database, contractors must determine whether the woman has ever received services funded by BCCS and has an existing Med-IT® ID (a unique number assigned to each BCCS client) by doing a client search. This process can be completed by entering patient identifiers, which may include name, date of birth, and/or social security number.

Minimum PC Requirements for Med-IT® are:

- Any internet connection – for optimum performance and response time, contractor locations should have access to a broadband connection with a minimum of 1 MB upload speed and 2 MB download speed; and
- Microsoft Internet Explorer 11.0 or above.

Med-IT® users must have access to the database and BCCS service providers must be listed in the database. New users may request access by completing the Med-IT New User Request (Form 5200). New providers must complete the Med-IT New Provider Request (Form 5201).

CHAPTER 3: CLINICAL POLICY

BCCS Contractor Clinical Responsibilities

Contractors must:

- accept referrals for breast and cervical cancer services, funds permitting;
- provide follow-up and navigation of clients with abnormal screening or diagnostic results;
- assist eligible clients in applying for MBCC, including eligible clients diagnosed outside the BCCS program;
- make a Good Faith Effort to obtain treatment for clients with a pre-cancerous or cancerous breast or cervical diagnosis who do not meet the eligibility criteria for BCCS Cervical Dysplasia and/or Medicaid for Breast and Cervical Cancer (MBCC);
- communicate with team members within your organization regarding program requirements of the BCCS program; and
- provide and document monitoring and oversight of subcontractors and subcontracted services to ensure compliance with BCCS policies and standards.

Covered Services

The Breast and Cervical Cancer Services program services include:

- screening services;
- clinical breast examination;
- mammogram;
- pelvic examination and pap test;
- diagnostic services;
- cervical dysplasia management and treatment; and
- if necessary, assistance completing the Medicaid for Breast and Cervical Cancer application.

Detailed information on available BCCS services is located in the BCCS Billing Guideline.

Client Health Record and Documentation of Patient Encounters

Individual Health Records and Documentation

Contractors must ensure that a patient health record (medical record) is established for every client who obtains BCCS services.

All patient health records must be:

- Complete, legible, written in ink, and/or documented within an Electronic Medical Record (EMR). No erasures or deletions should occur within a health record;
- Accurate documentation of all clinical encounters, including those by telephone;
- Signed by the provider making the entry, including name of provider, provider title, and date for each entry.
  - Electronic signatures are allowable to document provider review of care.
  - Stamped signatures are not allowable.
- Readily accessible to assure continuity of care and availability to patients; and
- Systematically organized to allow easy documentation and prompt retrieval of information.

All patient health records must include:

- Client identification, personal data and eligibility assessment (including insurance assessment);
- Preferred language/method of communication;
- Patient contact information with the best way to reach patient in such a manner that facilitates continuity of care, assures confidentiality, and adheres to Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations;
- A problem list, updated as needed at each encounter, indicating significant illnesses and medical conditions;
- A complete medication list, including prescription and non-prescription medications, as well as dietary supplements, updated at each encounter;
- A complete listing of all medication allergies and adverse reactions, and other allergic reactions, displayed in a prominent place, and confirmed or updated

at each encounter; if the person has no known allergies, this should be properly noted.

- Documentation of the individual's past medical history to include all serious illnesses, hospitalizations, surgical procedures, pertinent biopsies, accidents, exposures to blood products, and mental health history;
- An individual's health risk survey and assessment, including past and current tobacco, alcohol, and substance use/abuse, domestic and/or intimate partner violence and/or abuse (for any positive result, the individual must be offered referral to a family violence shelter in compliance with Texas Family Code, Chapter 91, occupational and environmental hazard exposure, environmental safety (e.g., seat belt use, car seat use, bicycle helmets, etc.), nutritional and physical activity assessment, and living arrangements, updated as appropriate at each encounter;
- At each encounter, an encounter-relevant history and physical examination pertinent to the person's reason for presentation;
- Assessment or clinical impression;
- Plan of care, consistent with diagnoses and assessments which in turn are consistent with clinical findings, including education/counseling, treatment, special instructions, scheduled visits and referrals;
- Appropriate laboratory and other diagnostic test orders, results, and follow-up as indicated;
- Documentation of recommended follow-up care, scheduled return visit dates, and follow-up for missed appointments;
- Documentation of informed consent or refusal of services, to include at a minimum:
  - General consent for care;
  - Informed consent for any surgical or invasive procedures as indicated;
  - For required or recommended services refused or declined by the person, documentation of the service offered, counseling provided, and the person's decision to decline;
- Documentation of client counseling and education, with attention to risks identified in the health risk assessment; and
- At every clinic visit, the record must be updated as appropriate, and the reason for the visit, any assessment made, and service provided must be documented.

Note: A comprehensive patient health record as described above does not have to be established for clients referred-in only for Medicaid for Breast and Cervical

Cancer (MBCC) assistance. For these clients, the BCCS contractor shall establish a Patient Navigation Record.

Counseling and Education

For every woman who receives breast and/or cervical cancer screening and/or diagnostic services through BCCS, the service provider must effectively communicate and document the following information during the initial visit and update during follow-up visits as indicated by the client's risk assessment:

- Risk factors for breast and cervical cancer;
- Signs and symptoms of breast and cervical cancer;
- Importance of cancer screening at regular intervals;
- Limitations of screening, including limitations of imaging in women with dense breasts for breast services;
- Information on HPV and safe sex practices; and
- Information on the HPV vaccine for cervical services;
- BCCS services and eligibility may change from year to year; and
- Tobacco cessation information and quit line referral, if appropriate.

Tobacco Assessment and Quit Line Referral

All women receiving BCCS services must be assessed for tobacco use. Women who use tobacco should be referred to tobacco quit lines. The Texas American Cancer Society Quit Line is 1-877-YES-QUIT or 1-866-228-4327 (Hearing Impaired). The assessment and referral should be performed by agency staff and documented in the clinical record.

Requirements for Policies to Ensure Appropriate Follow-up and Continuity of Care

Follow-up of Breast and Cervical Screening Results

The clinician must notify a woman of findings, reinforce the need for continued routine screening examination and provide the expected interval for her next routine screening examination. Contractors must attempt to notify each woman in writing of her regular screening due date.

Rescreening Eligibility

Rescreening is the process of returning for a breast and/or cervical cancer screening test at a predetermined interval (as per program guidelines) when no

symptoms are present.

Women may return for rescreening if they continue to meet BCCS financial and clinical eligibility requirements. Women with a history of cancer may return for screening when they conclude their cancer treatment, if they continue to meet BCCS financial and clinical eligibility requirements.

Exceptions to Rescreening

Contractors are not required to rescreen a woman if the contractor has documented that she:

- Cannot be located or has moved from the contractor's service area;
- No longer meets the BCCS financial or clinical eligibility;
- Has Medicare Part B or other adequate health insurance which provides coverage for breast and/or cervical cancer screening and diagnostic testing;
- Refuses (in writing or verbally) to return for BCCS services;

Prescriptive Authority Agreements

When services are provided by Advanced Practice Registered Nurse(s) and/or Physician Assistant(s), it is the responsibility of the contractor to ensure that a properly executed prescriptive authority agreement (PAA), as required by Texas Administrative Code Title 22, Part 9, Chapter 193, is in place for each such provider. This is true whether the provider is employed by the contractor or is providing services by subcontract with or referral by the contractor. The PAA must meet all the requirements delineated in the Texas Occupations Code, Chapter 157.

The PAA need not describe the exact steps that an advanced practice registered nurse or physician assistant must take with respect to each specific condition, disease, or symptom. The PAA and any amendments must be reviewed at least annually, dated, and signed by the parties to the agreement. A copy of the current PAA must be maintained on-site where the advanced practice registered nurse or physician assistant provides care.

Standing Delegation Orders

Contractors must ensure that all clinical services are provided in compliance with statutes and rules governing medical and nursing practice consistent with national evidence-based clinical guidelines. When BCCS revises a policy, contractors need to incorporate the revised policy into their written protocols, standing delegation orders (SDOs), and procedures.

Standing Delegation Orders

When services are provided by unlicensed and licensed personnel, other than advanced practice nurses or physician assistants, whose duties include actions or procedures for a patient population with specific diseases, disorders, health problems or sets of symptoms, must have written standing delegation orders (SDOs) in place. SDOs are distinct from specific orders written for a particular individual. SDOs are instructions, orders, rules, regulations or procedures that specify under what set of conditions and circumstances actions should be instituted. The SDOs delineate under what set of conditions and circumstances an RN, LVN, or non-licensed healthcare provider (NLHP) actions or tasks may be initiated in the clinical setting and provide authority for use with individuals when a physician or advance practice provider is not on the premises, and or prior to being examined or evaluated by a physician or advanced practice provider. Example: SDO for assessment of Blood Pressure which includes an RN, LVN or NLHP that will perform the task, the steps to complete the task, the normal/abnormal range, and the process of reporting abnormal values.

Other applicable SDOs when a physician is not present on-site may include, but are not limited to:

- obtaining a personal and medical history;
- performing an appropriate physical exam and the recording of physical findings;
- initiating/performing laboratory procedures;
- administering or providing drugs ordered by voice communication with the authorizing physician;
- handling medical emergencies – to include on-site management as well as possible transfer of client;
- giving immunizations; or
- performing pregnancy testing.

The SDOs must be reviewed, signed, and dated by the supervising physician who is responsible for the delivery of medical care covered by the orders and other appropriate staff, at least annually and maintained on-site.

Breast Cancer Screening Eligibility

Breast screening refers to procedures including clinical breast examination (CBE), screening mammogram and MRI for women who present without symptoms suspicious for breast cancer.

*Note that the recommendations for frequency of mammography screening described above come from the US Preventive Services Task Force Recommendation Statement on Screening for Breast Cancer. The National Comprehensive Cancer Network recommends annual screening mammography be offered to all asymptomatic women 40 years of age and older. Links to both guidelines are provided in the References section immediately below.

Reimbursement guidelines for mammography screening:

- Ages 40 and older: Women may be screened annually.
- Ages under 40: Asymptomatic and without a history of breast cancer are not eligible for breast cancer screening services.
- Note: Contractors must document high-risk assessment and any screening guideline exceptions for women ages 40-49 within Med-IT cycle notes.

Transgender Clients

Transgender women (male-to-female) that meet all program eligibility requirements are eligible to receive breast cancer screening and diagnostic services. Transgender men (female-to-male) may receive cancer screening if they meet program eligibility requirements.

The Center of Excellence for Transgender Health and the World Professional Association for Transgender Health have developed consensus recommendations on preventive care services for the transgender population. Those recommendations include for "transwomen with past or current hormone use, breast-screening mammography in patients over age 50 with additional risk factors (e.g., estrogen and progestin use > 5 years, positive family history, BMI > 35)." Those preventive care recommendations can be found at https://transcare.ucsf.edu/guidelines/breast-cancer-women.

BCCS recommends that grantees and providers counsel all eligible women, including transgender men and women, about the benefits, potential harms, and limitations of screening and discuss individual risk factors to determine if screening is medically indicated.

Components of Breast Cancer Screening

The contractor must provide a complete breast cancer screening, which includes a mammogram, individualized client education, tobacco use assessment and Quit Line referral if indicated, and may include a clinical breast examination (CBE). The contractor must document the breast cancer screening components in the client's record and Med-IT®.

A breast health history must be included as part of the breast cancer screening. The health history includes:

- Date and time intervals of previous mammograms;
- Results of previous mammograms;
- Date and results of the last CBE;
- Date and results of any previous breast surgery;
- Date of last menstrual period;
- Medication history, including current or previous use of hormones (hormone replacement therapy, oral contraceptives, etc.);
- Other risk factors for breast cancer (personal history of breast cancer, or family history of first degree relatives with breast cancer); and
- Description of breast symptoms, if any.

Clinical Breast Examination (CBE)

A CBE is not a pre-requisite for reimbursement for a screening mammogram by the BCCS program. Grantees should document if a CBE is not indicated for Minimum Data Element (MDE) records. CBEs must be performed by a physician, physician's assistant, nurse practitioner, certified nurse midwife, or additionally a qualified registered nurse with specialized training as required under standing delegation orders (SDO). The specialized RN CBE training must be documented in the personnel record (e.g. an educational certificate/degree or continuing education). Complete documentation of the CBE must be included in the patient health record and Med-IT.

A CBE is required prior to diagnostic testing, but a repeat CBE is not required for women referred to a BCCS contractor after an abnormal CBE or screening mammogram.

Screening Mammogram Special Circumstances

Additional views as used with a diagnostic mammogram (4-6 specified diagnostic views) can be used to screen women with the following special circumstances:

- Women with cosmetic or reconstructive breast implants; and/or
- Women with history of breast cancer and lumpectomy (partial mastectomy).

Screening Magnetic Resonance Imaging (MRI)
Breast MRI may be reimbursed by BCCS in conjunction with a screening mammogram after program approval. Contractors must request approval using the Breast MRI Pre-Authorization Request Form.

Women at high risk for breast cancer should undergo both screening MRI and screening mammogram annually. Women considered high risk for breast cancer include anyone with one or more of the following risk factors:

- A BRCA mutation;
- A first-degree relative who is a BRCA carrier;
- A lifetime risk of 20-25 percent or greater as defined by risk assessment models; or
- Radiation therapy to the chest when they were between the ages of 10 and 30 years.

Breast MRI can also be reimbursed when used to better assess areas of concern on a mammogram or for evaluation of a client with a history of breast cancer after completing treatment

Magnetic Resonance Imaging: Restrictions

- Breast MRI must never be performed alone as a breast cancer screening tool.
- Breast MRI cannot be reimbursed to assess the extent of disease for staging in women already diagnosed with breast cancer.
- All breast MRI procedures require pre-authorization.
- Pre-authorization form must be received **a minimum of three (3) business days** prior to the anticipated procedure date.
- MRI procedures must be performed in facilities with dedicated breast MRI equipment able to perform MRI-guided breast biopsies.

Imaging Reports – Screening mammogram/MRI

Radiology facilities must prepare a written report of the results of each radiologic examination, including screening mammography and MRI. This report must include

the following:

- The name of the client and an additional client identifier;
- The name of the physician who interpreted the mammogram; and
- An overall final assessment of findings utilizing the BIRADS system of classification.

Breast Cancer Diagnostic Services

Breast Cancer Diagnostic Eligibility

Applicants ages 18 to 64 may be eligible for breast cancer diagnostic services if they have an abnormal breast cancer screening result and meet program eligibility requirements.

Managing Women with Abnormal Breast Cancer Screening Results

The management of women whose mammogram and/or CBE are abnormal relies on a body of scientific literature that is constantly growing and changing. Providers should follow standards established by such organizations as the National Comprehensive Cancer Network (https://www.nccn.org) and the American College of Radiology (http://www.acr.org/).

Reimbursement for Complications of Breast Procedures

Contractors may request reimbursement for treatment costs associated with patient complications related to breast biopsy procedures that occur in the immediate post-procedure or post-operative period, excluding inpatient hospital services. Contractors may be reimbursed through a voucher system for approved charges up to $3000 per occurrence from awarded contract funds. To request reimbursement, contractors must email the Breast and Cervical Diagnostic Procedure Complication Reimbursement Request Form and supporting documents to BCCS program staff at BCCSprogram@hhsc.state.tx.us.

Supporting Documents include:

- The client's Med-IT® ID and date of service when treatment procedure(s) were performed on the client in question;
- A narrative summary detailing the breast biopsy procedure performed and any related complications which have been documented in the Navigation or Cycle Note section of the client's Med-IT® record;

- All emergency room, surgical, and progress notes, etc. for the client related to complications of the procedure;
- The procedure note and/or operative report, etc. for the initial procedure; and
- A completed paper CMS-1500 form detailing the procedures for which the contractor is seeking reimbursement (list all procedures related to the complication even if they are not typically reimbursable under the BCCS Program)

References

- Siu, AL. Screening for breast cancer: US Preventive Services Task Force Recommendation Statement. *Ann Intern Med.* 2016;164(4):279-296. Available at http://annals.org/article.aspx?articleid=2480757 (web)
- National Comprehensive Cancer Network. (2018). NCCN clinical practice guidelines in oncology: Breast cancer screening and diagnosis. Version 2.2018. Available at https://www.nccn.org/professionals/physician_gls/f_guidelines.asp#breast_screening

Cervical Cancer Screening Services

The cervical cancer priority population includes women who have never been screened. If necessary, recruitment efforts should be concentrated on the priority population. For cervical cancer screening to be most effective, the screening must be conducted at *regular intervals*.

Cervical Cancer Screening Management

Cervical cancer screening is primarily performed using the Pap test and the HPV DNA test. BCCS utilizes United States Preventive Services Task Force (USPSTF) cervical cancer screening recommendations.

Clinical and reimbursement guidelines for cervical screening:

- Ages 21-29: Cervical cytology (Pap smear) alone every three (3) years, with reflex human papillomavirus (HPV) testing when cytology reveals atypical squamous cells of undetermined significance (ASCUS).
- Ages 30-64: Cervical cytology (Pap smear) alone every three (3) years, with reflex HPV testing for ASCUS or cervical cytology and HPV co-testing every five (5) years (preferred).

- Ages under 21: Not eligible for cervical cancer screening.

Special Circumstances

Special circumstances may warrant alterations in screening intervals as determined by a clinician. Special circumstances must always be documented in Med-IT cycle notes. These may include:

- Clients considered high-risk (e.g. HIV+, immunosuppressed, exposed to Diethylstilbestrol (DES) in utero, history of cervical cancer, etc.);
- Clients who had a hysterectomy for CIN disease may continue screening for 20 years;
- Clients who have had cervical cancer may be screened indefinitely as long as they are in good health; and,
- Applicants who have had a hysterectomy for benign disease and the cervix is still present may be eligible for cervical cancer screening services. Funds can be used to pay for an initial examination to determine if the cervix is still present.

Transgender Clients

Transgender men (female-to-male) who have a cervix may receive BCCS cervical cancer screening services if other eligibility criteria are met. Transgender women (male-to-female) are not eligible for cervical services.

Components of Cervical Cancer Screening

The clinical components of cervical cancer screening are pelvic examination, Pap test, HPV test if indicated, clinical breast exam (CBE), client education, tobacco assessment, and Quit Line referral, if indicated. The contractor must document the CBE and cervical cancer screening components in the client's record and Med-IT.

A cervical health history must be included as part of the cervical cancer screening. The health history includes:

- Date and results of the last pelvic examination and Pap test;
- Date and results of any past diagnostic procedure(s) and/or treatment(s) for cervical disease;
- Date of last menstrual period and pregnancy history;
- Medication history, including current or previous use of hormones (hormone replacement therapy, oral contraceptives, etc.);
- Risk factors for cervical cancer; and

- Description of present pelvic symptoms.

Clinical components of cervical cancer screening must be performed by a physician, physician's assistant, nurse practitioner, certified nurse midwife, or a qualified registered nurse with specialized training as required under SDOs. The RN's specialized training for cervical cancer screening must be documented in the personnel record (e.g. an educational certificate/degree or continuing education).

Contractors must have policies and procedures to ensure healthcare providers follow evidence-based clinical guidelines and/or provide clinical services consistent with current nationally recognized standards of care.

HPV Testing

HPV DNA testing is a reimbursable procedure when used for screening with Pap testing (i.e., co-testing) and for follow-up of abnormal Pap results as per the American Society for Colposcopy and Cervical Pathology (ASCCP) algorithms.

- Reimbursement for low-risk HPV DNA panel is not permitted;
- HPV tests must be FDA approved and clinically validated.

Cervical Cancer Diagnostics

Cervical Cancer Diagnostic Eligibility

Applicants ages 18-64 who meet BCCS general requirements may receive diagnostic services. BCCS funded diagnostics services must be delivered according to the ASCCP guidelines.

Follow-up for Abnormal Cervical Screening

When the pelvic exam and/or cervical cancer screening test (Pap test) results are abnormal, further diagnostic follow-up is required. A normal Pap test does not rule out cancer if a woman has a cervical lesion on pelvic examination. A colposcopy and/or cervical biopsy are allowed if determined appropriate by the clinician after an abnormal pelvic exam.

BCCS contractors must follow the algorithms for the management of the specific type of abnormal result and in consideration of special populations (e.g. pregnant women and clients age 20 years and younger or at high risk).

Components of Cervical Cancer Diagnostics

Diagnostic Procedures -Tests performed to confirm or rule out cancer when screening tests yield abnormal results include: colposcopy, cervical biopsy, endocervical curettage (ECC), and diagnostic excisional procedures. CBE is not required when a client is referred to BCCS after an abnormal pelvic exam or abnormal Pap test. Diagnostic procedures must be performed by qualified clinicians with specialized training (physicians, physician's assistants, nurse practitioners or certified nurse midwives).

Clinical Utilization Restrictions for Diagnostic Procedures

Diagnostic LEEP conization, laser conization, and cold knife conization cannot be performed on the following clients:

- Any age in the absence of HSIL, ASC-H or higher abnormality; and,
- Any age with histology CIN I or lesser abnormality for a duration of less than two years and in the absence of HSIL or atypical glandular cells (AGC) on Pap tests.

Other Restrictions

The BCCS Program will monitor the use of facility/anesthesia services for cold knife conization, as well as utilization for LEEP.

Contractors are encouraged to develop subcontracts with practitioners having specialized training in the management of cervical disease including LEEP as an office-based procedure.

Consultations

Consultations for follow-up of abnormal cervical results must be performed by healthcare providers with specialized training in the management of cervical disease, including skill performing invasive diagnostic procedures.

A consultation can only be performed by a healthcare provider who did not perform the original screening examination. If that healthcare provider is not a licensed physician, appropriate protocols must be established and documented for that provider. Consultations **must** involve direct examination of the client and are billed using office visit codes.

Access to Treatment

The following treatment options may be available for eligible clients with a qualifying diagnosis:

- General Revenue funds for Cervical Dysplasia Management and Treatment of clients who have qualifying diagnoses and are not eligible for MBCC. For a description of qualifying diagnoses, see the chapter entitled "Cervical Dysplasia Management and Treatment".
- Medicaid for Breast and Cervical Cancer (MBCC) for applicants who have qualifying breast or cervical cancer diagnoses and meet all other MBCC eligibility criteria. See chapter entitled "Medicaid for Breast and Cervical Cancer (MBCC)" and MBCC Guidelines for Determination of Qualifying Diagnosis for guidance.

Office-Based Procedures Performed in an Ambulatory Surgical Center

Special circumstances may arise that necessitate an office-based diagnostic procedure being performed in an ambulatory surgical center. These services require pre-authorization PRIOR to the client receiving services in an ambulatory surgical center or other outpatient facility. Contractors must submit the Office-based Procedures Performed in an Ambulatory Surgical Center Pre-authorization Form, along with any supporting documentation to BCCSprogram@hhsc.state.tx.us **a minimum of three (3) business days prior to the anticipated date of the procedure**. BCCS will not reimburse for any office-based procedures performed in an ambulatory surgical center that have not received pre-authorization. Evidence of pre-authorization approval must be made available to BCCS review staff during Monitoring on-site visits. *Special circumstances may include clients with a history of cervical cancer, obesity, cervical stenosis, vaginal stenosis or atrophy.*

Reimbursement following complications of LEEP and LEEP Conization Procedures

Contractors may request reimbursement for treatment costs associated with patient complications related to LEEP and conization procedures that occur in the immediate post-procedure or post-operative period, excluding inpatient hospital services. Contractors may be reimbursed through a voucher system for approved charges up to $3000 per occurrence from awarded contract funds. To request reimbursement, contractors must email the Breast and Cervical Diagnostic Procedure Complication Reimbursement Request Form and supporting documents to BCCS program staff at the email box designated by program.

Supporting Documents include:

- The client's Med-IT® ID number and date of service when treatment procedure was performed on the client in question;
- A narrative summary detailing the LEEP/conization procedure performed and any related complications which have been documented in the Case Management or Cycle Note section of the client's Med-IT® record;
- All emergency room, surgical, and progress notes for the client related to complications of the procedure;
- The procedure notes and/or operative report for the initial procedure; and
- A completed paper CMS-1500 Health Insurance Claim Form detailing the procedures for which the contractor is seeking reimbursement (list all procedures related to the complication even if they are not typically reimbursable under the BCCS Program).

Cervical Dysplasia Management and Treatment

CDC strictly prohibits reimbursement of treatment services; however, contractors may receive limited state funding for management and treatment of cervical dysplasia (CD). CD procedures are reimbursed from non-federal funding, as NBCCEDP prohibits use of CDC grant funds for treatment. Cervical dysplasia funds may **not** be used to reimburse for BCCS cervical screening or diagnostic services.

Cervical Dysplasia Eligibility

Applicants meet BCCS general eligibility criteria and have a definitive, biopsy-confirmed diagnosis of one of the following diagnoses:

- CIN I, CIN II, CIN II-III; or,
- High-grade dysplasia (severe dysplasia/CIN III) or CIS

Contractors **must** assess clients with severe dysplasia/CIN III/CIS for MBCC eligibility before using CD funds to pay for treatment services. Undocumented applicants are eligible for CD services.

Components of Cervical Dysplasia Services

Cervical dysplasia management and treatment services may include:

- Follow-up testing and observation without treatment, e.g. cytology (Pap tests), HPV testing, colposcopy.
- Treatment using excision or ablation, e.g. cryotherapy, cervical conization.

- Patient Navigation– see Patient Navigation Services.

Reimbursement for Cervical Dysplasia Management and Treatment Services

Reimbursement for cervical dysplasia services is limited to the codes which begin with "CD", "FCX", and "FCD" listed separately in the BCCS Billing Guidelines. These codes must be billed in the Med-IT system. Contractors should bill CD services throughout the dysplasia plan of care and return clients to BCCS services once released to routine screening intervals by the provider.

BCCS contractors must submit specimens for program covered laboratory testing to a US CLIA certified laboratory and adhere to all quality management requirements for cytology quality assurance.

Office-based Procedures Performed in an Ambulatory Surgical Center

Special circumstances may arise that necessitate an office-based diagnostic procedure being performed in an ambulatory surgical center. These services require pre-authorization PRIOR to the client receiving services in an ambulatory surgical center or other outpatient facility. Contractors must submit the Office-based Procedures Performed in an Ambulatory Surgical Center Pre-Authorization Form along with any supporting documentation to BCCSprogram@hhsc.state.tx.us **a minimum of three (3) business days prior to the anticipated date of the procedure**. BCCS will not reimburse for any office-based procedures performed in an ambulatory surgical center that have not received pre-authorization. Evidence of pre-authorization approval must be made available to BCCS review staff during Monitoring on-site visits. A special circumstance may be an abnormal pelvic exam, a client with a history of cervical cancer, obesity, cervical stenosis, vaginal stenosis or atrophy.

Medicaid for Breast and Cervical Cancer

The Health and Human Services Commission (HHSC) administers the Medicaid for Breast and Cervical Cancer (MBCC) Program, a special Medicaid program authorized by federal and state laws to provide access to cancer treatment services through full Medicaid benefits to qualified women.[4,5,6]

[4] 42 C.F.R. §435.213
[5] Human Resources Code Section §32.024(y) and (y-1)
[6] Title 1 of the Texas Administrative Code Chapter 366, Subchapter D

Medicaid for Breast and Cervical Cancer Eligibility

Applicants who need treatment must meet each of the following criteria:

- Diagnosed by a BCCS contractor or diagnosed by any physician and referred to a BCCS contractor for the application process;
- Have a qualifying diagnosis;
- At or below 200 percent of the federal poverty level; and
- Be uninsured, that is, she must not otherwise have creditable coverage. Creditable coverage is health care coverage that covers treatment for breast and cervical cancer, including current enrollment in Medicaid or Medicare Part A, Part B, or Part A & B.
  - Note: If the woman is enrolled in the Healthy Texas Women (HTW) Program at the time of diagnosis, she will be dis-enrolled from HTW in order to be enrolled in MBCC by Medicaid eligibility staff; and
- Under age 65; and
- U.S. citizen or eligible immigrant; and
- Texas resident.

Need Treatment

An individual is considered to need treatment for breast or cervical cancer if the initial screen under BCCS or, subsequent to the initial period of eligibility, the individual's treating health professional determines that:

1. Definitive treatment for breast or cervical cancer is needed, including treatment of a precancerous condition or early stage cancer, and including diagnostic services as necessary to determine the extent and proper course of treatment; and

2. More than routine diagnostic services or monitoring services for a precancerous breast or cervical condition are needed.

Disease surveillance is not considered to be active treatment for new applicants.

Clients receiving hormonal treatment and/or breast reconstruction are considered to be receiving treatment and ***may remain eligible*** for MBCC benefits if the client had initial treatment paid for by Medicaid. Clients with triple negative receptor breast cancer (TNRBC) receiving active disease surveillance are also considered to be receiving treatment and ***may remain eligible*** for MBCC benefits if active treatment was paid for by MBCC.

Active disease surveillance (for the purposes of determining eligibility for MBCC) is periodically monitoring disease progression to quickly treat cancerous and precancerous conditions arising from the presence of a previously diagnosed breast or cervical cancer.

Verification of Citizenship and Identity

As part of Public Law 109-171, Deficit Reduction Act of 2005, individuals declaring to be a United States (U.S.) citizen or nationals of the U.S. must provide evidence of citizenship when applying for or receiving Medicaid benefits. Documented verification must establish both citizenship and identity. The Medicaid citizenship and qualified immigrant rules apply to MBCC. In general, to be eligible for Medicaid an individual must either be a U.S citizen or a qualified immigrant.

Citizenship guidelines and verification requirements may be found at https://hhs.texas.gov/laws-regulations/handbooks/twh/part-a-determining-eligibility/a-300-citizenship.

If an applicant states that she is a citizen or legal immigrant, indicate on the last page of Form H1034 that she is **presumptively eligible**. If the BCCS Contractor (or health provider) is uncertain whether a woman meets citizenship and eligible immigrant requirements, the completed H1034 should be submitted for processing and determination, along with any citizenship or immigration documents the woman provides. If an applicant states that she does not meet citizenship requirements, an MBCC application may not be submitted.

For assistance with client eligibility and citizenship determination, call 2-1-1 or 1-877-541-7905.

Presumptive Eligibility

Presumptive eligibility is a Medicaid option that allows states to enroll women in Medicaid for a limited period before a full citizenship or legal immigrant eligibility determination is complete. Presumptive eligibility facilitates the prompt enrollment and immediate access to services for women who need treatment for breast or cervical cancer. The earliest date presumptive eligibility may begin is the day after the client received a biopsy-confirmed qualifying diagnosis.

Coverage

The earliest date a woman may be enrolled in full Medicaid coverage through MBCC is the day after a biopsy-confirmed qualifying diagnosis. Coverage may continue

through the duration of her cancer treatment. MBCC services are not limited to the treatment of breast or cervical cancer. If a client has a question about their Medicaid benefits or wants to locate a Medicaid provider in their area, they can call the TMHP Medicaid Client Help Line at 1-800-335-8957.

A client can continue to receive full Medicaid benefits if they meet the eligibility criteria and provide proof from their treating physician that they are receiving active treatment for breast or cervical cancer by returning Form H1551, Treatment Verification, along with Form H2340, Medicaid for Breast and Cervical Cancer Renewal, to HHSC before the end of the 6-month coverage renewal period.

If the client's cancer is in remission and the physician determines that the client only requires routine health screenings (e.g. annual breast examinations, mammograms and pap tests as recommended by the American Cancer Society and/or the US Preventative Services Task Force), the client is not considered to be receiving treatment and MBCC coverage would not be renewed. If a client is later diagnosed with a new breast or cervical cancer, recurrence of breast or cervical cancer, or metastasis related to the primary qualifying diagnosis, she may re-apply for MBCC.

MBCC Responsibilities

BCCS State Office Responsibilities

BCCS program staff are responsible for reviewing the clinical documents and other required documents and submitting the information to HHSC Centralized Benefits Services (CBS) within 3-5 business days of receipt of the complete application package. **Once submitted for consideration at HHSC Centralized Benefits Services, BCCS staff cannot review application status and does not assist with or collect documents for pended MBCC applications.**

HHSC MBCC Eligibility Staff Responsibilities

HHSC CBS staff verify receipt of the H1034 application within 48 hours and process the application within two business days of receipt. If additional information is required, clients are placed on MBCC Presumptive and allowed 10 days to provide the required information. Eligibility for all applications will be determined within 45 calendar days of receipt of the application packet.

Form TF0001, Notice of Case Action, is sent the same day eligibility is determined. This notice informs clients of their Medicaid status with an effective date of coverage and notifies the client of their Medicaid Eligibility Determination Group

number. Clients may contact 2-1-1 to request the status of their application and Medicaid number.

MBCC inquiries (from BCCS contractors) on client reinstatements, approvals, denials and final application status should be sent to CBS_MBCC@hhsc.state.tx.us.

BCCS Contractor Responsibilities

BCCS contractors are responsible for assisting women with completion of Form H1034, Medicaid for Breast and Cervical Cancer application, determining presumptive eligibility for qualified women, and assessing patient navigation needs. In situations where a BCCS contractor or subcontractor is unsure about a cancer diagnosis, the first step should be:

1. Review Guidelines for Determination of Qualifying Diagnosis;
2. If still unclear, the contractor should consult with their Medical Director or physician/provider staff regarding the diagnosis

BCCS contractors should not submit a diagnosis to the BCCS Clinical team or BCCS Staff for evaluation prior to submitting an MBCC application. If contractors submit applications to BCCS which are known to be ineligible for MBCC, BCCS may withhold or recover payment.

Initial BCCS contractor/subcontractor responsibilities:

- Collection and review of documents to ensure eligible income, age, insurance, citizenship and biopsy-confirmed qualifying diagnosis;
  - Do not send bills, tax forms, or other financial statements or information to BCCS. Contractors shall retain proof of income in client record and document financial eligibility in Med-IT.
  - Verify that analysis of all biopsies has been performed by a US CLIA certified laboratory.
  - Verify the date of specimen collection is documented (specimen collection date is typically found on the Pathology report, Operative record, or Procedure note);
- Assistance with the completion of the medical assistance application, Form H1034;
  - The name on Form H1034 must match the name on the client's social security card or legal identification. If names differ, contractors must provide clarification.

  - Write Driver's License and Alien ID numbers on the copy of the identification cards.
- Complete Med-IT data entry and billing prior to submitting the completed MBCC application to BCCS, including the Final Diagnosis and Treatment Screen for clients diagnosed with BCCS funds. The specific name of the treatment facility will be needed to facilitate closing out the cycle in Med-IT and for CDC reporting. Contact the Med-IT Data System Helpdesk (med-ithelpdesk@hhsc.state.tx.us) to add facilities to Med-IT.

BCCS contractors must submit the MBCC application and other required documents to BCCS no later than two (2) working days from the date presumptive eligibility determination is made (certification date at the bottom of page 6 of the application).

Submitted MBCC Application documents include:

- Form H1034;
- **Final** biopsy confirmed report for the qualifying diagnosis. Preliminary or temporary reports of qualifying diagnoses will not be accepted;
- Any other supportive documents that may be necessary to verify the date of specimen collection and need for cancer treatment. (e.g. operative record, procedure note or progress notes);
- If the diagnosis is more than six months old submit **both** of the following:
  - Physician letter/office visit note or other documentation specifying need for active treatment; and
  - Recent medical tests supporting the need for active treatment.
- To support a metastatic or recurrent cancer diagnosis, send:
  - Final biopsy-confirmed report of the original breast or cervical cancer diagnosis.
  - Diagnostic report(s) (e.g. CT scan, biopsy report, etc.) which indicate disease is "compatible with" and/or "consistent with" an original qualifying breast or cervical cancer diagnosis. For example, a diagnosis such as "metastatic adenocarcinoma consistent with the prior breast primary" would be acceptable. Many metastatic or recurrent cancers may look the same; the primary does not need to be explicitly diagnosed.

Following MBCC application submission, contractors may locate the application status in the clients Med-IT record. Contractors may also email the client Med-IT ID number to BCCS to confirm receipt of the application and supporting documents to MBCCApps@hhsc.state.tx.us with subject line "Verify Receipt of MBCC Application."

Medicaid Reinstatement

A client previously enrolled in Medicaid under MBCC within the past 12 months, and who is no longer on Medicaid, but is still in active treatment or in need of active treatment for the original cancer may re-apply for MBCC. Reinstatements are handled directly by HHSC. The BCCS contractor may help the client by:

- Requesting Form H1551 (Treatment Verification Form) and Form H2340 by calling 2-1-1 or 1-877-541-7905;
- Assist with completing required documents; and/or
- Faxing the following documents to HHSC:
  - Form H1551 and form H2340; and
  - Citizenship and identity verification.

State-to-State Transfers

State-to-State transfers are handled directly by HHSC. Please complete the following steps:

- Do not complete Form H1034.
- Have client call 2-1-1 or 1-877-541-7905
- Have client request Out-of-State MBCC application Form **H2340-OS AND Out-of-State treatment verification Form H1550.** 2-1-1 will send the documents to the client to complete and return to HHSC.

Pathology Specimens

Pathology specimens (original slides) collected and evaluated outside the U.S must be reviewed by a US CLIA certified lab to determine a qualifying diagnosis. The BCCS program and the client cannot be billed for the reading and interpretation of the specimen submitted to a US CLIA lab.

Options for specimen transport are:

- Client transported; or
- Lab-to-lab transported.

Patient Navigation Services

Clients often face significant barriers to accessing and completing cancer screening and diagnostics. Patient navigation is a strategy aimed to reduce disparities by helping women overcome those barriers. Patient navigation is defined as individualized assistance provided to women to help overcome barriers and

facilitate timely access to quality screening and diagnostic services, as well as initiation of timely treatment services for those diagnosed with cancer.

Patient Navigation Activities

Although patient navigation services vary based on an individual client's needs, at a minimum, patient navigation for women served by the BCCS program must include the following activities:

- A written assessment of the client's barriers to cancer screening, diagnostic services, and initiation of cancer treatment.
- Client education and support.
- Resolution of client barriers (e.g., transportation, translation services).
- Client tracking and follow-up to monitor progress in completing screening, diagnostic testing, and initiating cancer treatment.
- Given the centrality of the client-navigator relationship, patient navigation must include a minimum of two, but preferably more, contacts with the client.
- Collection of data to evaluate the primary outcomes of patient navigation: client adherence to cancer screening, diagnostic testing, and treatment initiation. Clients lost to follow-up should also be tracked.

Assessment

Assessment is a cooperative effort between the client and patient navigator to examine and document the client's needs (diagnostic, treatment, and essential support services) through a process of gathering critical information from the client. The assessment includes consent and assurance of confidentiality between the client and Patient Navigator.

Planning

The plan uses short and long-term needs identified in the assessment to establish services planned, timeframes, and follow-up. As applicable, timeframes must be consistent with BCCS required screening and diagnostic intervals. Services must be completed no later than thirty (30) days from the date of the planned activity or prior to initiation of treatment, whichever is sooner.

Coordination

Coordination is the implementation of the service plan, including the appropriate use of available resources to meet the needs of the client. Coordination of services

may include scheduling appointments, making referrals, and obtaining and disseminating appropriate reports.

Monitoring

Monitoring is the ongoing assessment of the client's service plan to ensure that the client's needs are met. In addition to monitoring clients who are receiving patient navigation services, BCCS contractors must establish a system to monitor abnormal screening or diagnostic results for identifying clients who need to have patient navigation initiated.

Resource Development

Patient Navigators are responsible for identifying resources to meet client needs including dysplasia and cancer treatment services, regardless of client ability to pay. Documentation must be maintained in a resource directory developed specifically for detailing services that support BCCS-enrolled women with unmet needs.

Contractor Requirements

BCCS contractors must navigate:

- BCCS enrolled clients with abnormal screening or diagnostic results;
- Clients referred to BCCS with qualifying breast or cervical cancer diagnoses that are presumptively eligible for MBCC; and,
- Clients referred to BCCS for Cervical Dysplasia Management and Treatment. CD recipients must not be eligible for MBCC.

Patient navigation does not include eligibility determination or navigation of MBCC applicants whose presumptive eligibility determination was inaccurate.

Patient navigation is not required for:

- Clients with an abnormal CBE and/or screening mammogram followed by two normal diagnostic assessments/tests, e.g. diagnostic mammogram, ultrasound or referral to a breast specialist for a consultation where no further diagnostics are required.
- Clients with initial ASC-US unless colposcopy is indicated.

Terminating Patient Navigation

Depending on screening and diagnostic outcomes, patient navigation services are terminated when a client:

- Completes screening and has a normal result;
- Completes diagnostic testing and has normal results;
- When a referral appointment for treatment has been attended;
- Client is documented as lost-to follow up or refused services; and/or
- A Good Faith Effort has been made according to BCCS Policy; or
- Initiates cancer treatment or refuses treatment.

When a client concludes her cancer treatment and has been released by her treating physician to return to a routine screening schedule, she may return to the program and receive all services, including patient navigation, as long as she continues to meet BCCS eligibility requirements.

Requirements for Patient Navigation Compliance

- Patient Navigation must include assessment and client consent using the HHSC Comprehensive Patient Navigation Form. Agencies using alternate forms must maintain proof of HHSC approval onsite for Monitoring visits.
- A copy of the signed Patient Navigation Form must be maintained in the client's record. The assessment is to be conducted within 30 days from the date of referral for diagnostic procedures or prior to the initiation of the first diagnostic service, whichever is sooner.
- The assessment should be conducted in a face-to-face interview format, if possible. For non-face-to-face assessments, the client should sign and date the Patient Navigation Form upon their next visit to the agency.
- The service plan must be documented in the Med-IT Data System Navigation screen and the client's progress notes.
- Contractor must ensure that monitoring of abnormal results is conducted and documented at the contractor level.
- Contractor must contact clients with abnormal screening and non-cancerous diagnostic results no later than thirty (30) days following receipt of an abnormal result. All screening and diagnostic services must be documented; including procedure specific consent, if applicable.
- Contractor must contact clients with cancer diagnoses no later than two (2) weeks following the receipt of a cancer diagnostic result. All screening and diagnostic services must be documented; including procedure specific consent, if applicable.
- Within one month after completion of the patient navigation plan for a diagnosis of cancer or cervical dysplasia, the patient navigator must follow-up and document that the service was implemented.

- As additional needs are identified, they are recorded on the plan and the accompanying services and time frames are indicated.
- Contractors must develop and maintain a resource directory containing information on services that could support women with unmet needs who are eligible for BCCS, which may include Marketplace (www.Healthcare.gov) referral material.
- Contractors must document client refusal, lost to follow-up and Good Faith Effort as appropriate.

Navigation of MBCC Referrals

Referred-in MBCC applicants must be provided a needs assessment and MBCC application assistance if determined to meet presumptive eligibility. BCCS contractors may choose to provide patient navigation for MBCC referrals that were determined to be ineligible. If patient navigation is initiated for a client found to be ineligible for MBCC, BCCS contractors shall follow the client until treatment is initiated but may **not** bill BCCS for the patient navigation services provided. If patient navigation will not be initiated, the client should be provided with information about available local resources and referred to the diagnosing health professional.

Good Faith Effort

A Good Faith Effort is making at least three (3) separate documented attempts to obtain treatment for clients with a pre-cancerous or cancerous breast or cervical diagnoses who do not meet the eligibility criteria for CD and/or MBCC enrollment. Examples include, but are not limited to, seeking service(s) for clients through: American Cancer Society, Susan G. Komen for the Cure, LIVESTRONG or other healthcare providers and facilities through pro-bono, sliding fee scale, reduced payment plan, or sponsorship assistance.

Client Refusal of Services

The contractor must attempt to obtain in writing and document in the client record informed refusal from the client if the client fails to keep appointments or refuses recommended procedures. If the client cannot, or will not, sign an informed refusal the contractor must document verbal refusal. Before closing the client record as a refusal, a thorough review of the client's plan, recommendations and navigator's actions must be conducted to ensure proper closure.

Lost to Follow-Up

Before a contractor can consider a client as lost to follow-up, the contractor must have at least three separate documented attempts to contact the client, with the last attempt sent by certified mail. The contractor must allow sufficient time between contact attempts for the client to reply/respond to the contractor.

Client contact attempts can be made by:

- Office visit,
- Telephone,
- Home visit, and/or
- Mail.

Attempts to contact the client must be written or presented verbally (when appropriate) in the client's primary language, if limited English proficiency, including appropriate provisions for the visually and hearing impaired.

CHAPTER 4: REIMBURSEMENT

Billing Procedures for BCCS Contractors

Contractors must accept Fee-For-Service (FFS) payment rates for screening, diagnostic, and patient navigation services specified in Med-IT.

BCCS client data shall be entered in Med-IT no later than 30 days after provision of each service. BCCS services and procedures that have met business rules will be marked approved to pay and submitted electronically to HHSC for processing through the State Comptroller. Paid claims will be deposited into the contractor's direct deposit account. Contractors may only be reimbursed for services listed in the BCCS Billing Guideline.

Completed MBCC applications shall not be submitted to HHSC until all client data and patient navigation billing has been entered in Med-IT.

Funding for Screening Mammograms/MRI

Reimbursement for screening mammograms/MRI for high-risk asymptomatic women ages 40-49 must be initially billed using the B codes listed in the BCCS Billing Guideline.

BCCS funds may not be used for breast cancer screening in clients under the age of 40.

Funds for Cervical Dysplasia (CD) Management and Treatment

Federal funds may never be applied to treatment services. Cervical dysplasia funds should be used for cervical dysplasia management and treatment services for women who meet BCCS eligibility criteria and have a definitive diagnosis (biopsy confirmed) of:

- CIN I, CIN II, CIN II-III; or
- CIN III or CIS if the client does not meet eligibility criteria for Medicaid for Breast and Cervical Cancer (MBCC). CIN III/CIS results should always be screened for MBCC eligibility **prior** to CD treatment enrollment.

CHAPTER 5: DATA COLLECTION, REPORTING, AND PERFORMANCE

Financial Reconciliation Report (FRR)

The FRR is the annual reconciliation report submitted to HHSC. Each grantee must report final financial results as part of the closeout process on each contract. This report is due no later than 60 days after the end of the applicable contract term, or 30 days after the last pay file is run, whichever is later. Send completed form to the email box designated by program.

Match Report

Matching funds refer to non-federal resources (money and/or in-kind contributions). The CDC requires the BCCS program to provide $1 in match for every $3 CDC funding awarded. All BCCS contractors must secure, budget, expend, and report non-federal match. Match reports are submitted to HHSC 30 days after the end of each quarter.

Clinical Performance Measures

Contractors are required to meet NBCCEDP performance measures. The following performance measures are used to assess, in part, the contractor's effectiveness in providing BCCS services:

Screening Indicators:

- A minimum of 20 percent of all NBCCEDP-reimbursed screening Pap tests should be provided to program-eligible women who have never been screened for cervical cancer. Grantees may use either conventional or liquid-based cytology.
- A minimum of 75 percent of all NBCCEDP-reimbursed mammograms/MRIs should be provided to program-eligible women who are 50 years of age and older and not enrolled in Medicare-Part B.

Cervical Cancer Diagnostic Indicators:

- A minimum of 90 percent of abnormal cervical screening results must have a complete follow-up with no more than 10 percent lost to follow-up, refused, and/or pending.

- The interval between initial screening and diagnosis of abnormal cervical cancer screenings should be 90 days or less for a minimum of 75 percent of the women with abnormal results.
- A minimum of 90 percent of HSIL, CIN II, CIN III, CIS, and invasive cervical cancer diagnoses must have started treatment.
- The interval between diagnosis and initiation of treatment for HSIL, CIN II, CIN III and CIS should be 90 days or less for a minimum of 80 percent of the women needing treatment.
- The interval between diagnosis and initiation of treatment for invasive cervical cancer should be 60 days or less for a minimum of 80 percent of the women diagnosed.

Breast Cancer Diagnostic Indicators:

- A minimum of 90 percent of abnormal breast screening results must have a complete follow-up with no more than 10 percent lost to follow-up, refused, and/or pending.
- The interval between initial screening and diagnosis of abnormal breast cancer screenings should be 60 days or less for a minimum of 75 percent of women with abnormal results.
- A minimum of 90 percent of breast cancer diagnoses must have started treatment.
- The interval between diagnosis and initiation of treatment for breast cancer should be 60 days or less for a minimum of 80 percent of women needing treatment.
- Administrative Indicators
- Contractors must serve a minimum of 85 percent of proposed unduplicated clients;
- Contractors must expend a minimum of 95 percent of the awarded funds;
- Contractors must submit Quarterly Match reports 30 days after the end of each quarter.

Contractors must comply with and utilize an online database system (Med-IT®) to collect and process breast and cervical data, reports, and billing in accordance with the business requirements of the program, including Med-IT® data entry within 30 days of services provided.

CHAPTER 6: PROGRAM PROMOTION, OUTREACH, and INREACH

To provide inreach, outreach, and education to the community, each contractor must establish a comprehensive inreach, outreach, and education plan. This plan will include the determination of the priority population, a recruitment work plan, inreach and outreach methods, and an evaluation of the effectiveness of recruitment strategies. Resources for evidence based strategies can be found in The Community Guide and Cancer Control PLANET.

Contractors should have an array of materials and resources to aid in community awareness. Contractors must develop and maintain relationships with local partners/collaborators that can assist in the recruitment of the priority population.

Contractors must include in their outreach plans how they plan to do the following:

- Implement strategies to enroll clients in BCCS, including:
  - Identifying the priority populations to receive information;
  - Identifying the population(s) at highest risk for developing breast and/or cervical cancer; and
  - Establishing relationships with internal and external partners to reach eligible clients in the priority populations.
  - Implementing strategies to raise community awareness of MBCC including:
    - Educating partners such as subcontractors, other health care providers, community organizations, coalitions, and local advocacy groups about MBCC and how to appropriately refer a non-BCCS diagnosed client for MBCC screening; and
    - Educating clients diagnosed with breast or cervical cancer about MBCC eligibility requirements and how to apply for services.
  - Provide information to each eligible woman in her primary language;
  - Provide access to information that is culturally sensitive, linguistically appropriate, and available to the visually and hearing impaired;
  - Conduct outreach activities specifically for clients age 50-64 years if less than 75 percent of all mammograms are provided to women ages 50-64;
  - Conduct outreach activities specifically for clients who have never received cervical cancer screening if less than 20 percent of clients newly enrolled for cervical cancer screening have never had a pap test;
  - Collect information describing how clients learned about BCCS, and enter

data into the Med-IT Data system using the "Learned of Program" function on the enrollment screen; and

- Submit the agency's comprehensive outreach and education plan within 45 days after the start of each contract term. Submit plans to BCCSprogram@hhsc.state.tx.us.

SECTION IV – FAMILY PLANNING PROGRAM POLICIES

CHAPTER 1: CLIENT ELIGIBILITY

Eligibility Guidelines

Eligible individuals must be:

- females and males age 64 years and younger;
- Texas residents. Residency is self-declared. Contractors may require residency verification, but such verification should not jeopardize delivery of services;
- at/or under 250 percent of the federal poverty level (FPL). Contractors must require income verification. If the methods used for income verification jeopardize the individual's right to confidentiality or impose a barrier to receipt of services, the contractor must waive this requirement. Reasons for waiving verification of income must be noted in the individual record.
- For un-emancipated, unmarried individuals under 18 years of age, if parental consent is required for the receipt of services per Section 32 of the Texas Family Code, the family's income must be considered in determining the charge for the service.
- If parental consent is not required to provide services to an individual under 18 years of age, per Section 32 of the Texas Family Code, only the individual's income is used to assess eligibility, not the income of other family members. In this case, the minor's own income is applied, and the size of the family should be recorded as one.
- If a barrier to receiving FPP services exists, the contractor may waive the requirement and approve full eligibility.

For determining FPP eligibility, the following definitions will be used:

Household

The household consists of a person living alone or a group of two or more persons related by birth, marriage including common-law, or adoption, who reside together and are legally responsible for the support of the other person. Household is self-declared.

For example: If an unmarried applicant lives with a partner, ONLY count the partner's income and children as part of the household IF the applicant and his/her partner have mutual children together. Unborn children should also be included. Treat applicants who are 18 years of age as adults. No children aged 18 and older or other adults living in the household should be counted as part of the household group.

Income

All income received must be included. Income is calculated before taxes (gross). Include sources of income as defined in the HHSC FPP Definition of Income.

- For individuals who are married or who are 18 years of age or older, the income of all family members must be used.
- For un-emancipated, unmarried individuals UNDER 18 years of age, if parental consent is required for the receipt of services per Section 32 of the Texas Family Code, the family's income must be considered in determining the charge for the service.
- If parental consent is not required to provide services to an individual UNDER 18 years of age, per Section 32 of the Texas Family Code, only the individual's income is used to assess eligibility, not the income of other family members. In this case, the minor's own income is applied, and the size of the family should be recorded as one.

Income Deductions

Dependent care expenses shall be deducted from total income in determining eligibility. Allowable deductions are actual expenses up to $200.00 per child per month for children under age 2 and $175.00 per child per month for each dependent age 2 or older.

Legally obligated child support payments made by a member of the household group shall also be deducted. Payments made weekly, every two weeks or twice a month must be converted to a monthly amount by using one of the conversion factors listed below.

Monthly Income Calculation

- If income is received in lump sums or at longer intervals than monthly, such as seasonal employment, the income is prorated over the period of time the income is expected to cover.
- Weekly income is multiplied by 4.33.

- Income received every two weeks is multiplied by 2.17.
- Income received twice monthly is multiplied by 2.

Eligibility Screening Process

HHSC FPP contracted agencies must screen all family planning applicants for eligibility in the following programs that provide family planning services in this order: Medicaid, Healthy Texas Women (HTW), and then the HHSC FPP. Eligibility screening criteria and processes are described below.

Screening for Medicaid

If the individual has a "Your Texas Benefits" Medicaid card, it can be used to document Medicaid eligibility.

Providers can call TMHP at 1-800-925-9126 or log on to TexMedConnect to check the member's Medicaid ID number (PCN).

Screening for HTW

All women 15-44 years of age who are not eligible for full Medicaid services must be screened for HTW. HTW is a state-funded program administered by HHSC to provide eligible uninsured women with women's health and family planning services such as woman's health exams, health screenings, and birth control. HTW providers must provide clinical services on a fee-for-service basis, and may also, but are not required to, contract with HHSC to provide support services that enhance clinical service delivery on a cost reimbursement basis.

HTW is for women who meet the following qualifications:

- ages 15-44
  - applicants ages 15-17 must have a parent or legal guardian apply, renew, and report changes to her case on her behalf (an applicant is considered 15 years of age the first day of the month of her 15th birthday and 17 years of age through the day before her 18th birthday);
  - an applicant is considered 18 years of age on the day of her 18th birthday and 44 years of age through the last day of the month of her 45th birthday;
- U.S. citizens and eligible immigrants;
- reside in Texas;
- do not currently receive full Medicaid benefits, Children's Health Insurance Program (CHIP), or Medicare Part A or B;

- are not pregnant;
- do not have private health insurance that covers family planning services, unless filing a claim on the health insurance would cause physical, emotional or other harm from a spouse, parent, or other person; and
- have a countable household income at or below 200 percent of the federal poverty level.

How to know if a person is covered by HTW:

If the individual has a "Your Texas Benefits" Medicaid card, it can be used to document Medicaid eligibility.

Providers can call TMHP at 1-800-925-9126 or log on to TexMedConnect to check the member's Medicaid ID number (PCN).

Contractors must assist individuals who screen eligible for HTW to complete the HTW Application Form #H1867 and verify the person's income, identity, and citizenship in accordance with HTW policies. An applicant may qualify as adjunctively eligible if she or a member of her family participates in the Special Supplemental Nutrition Program for Women, Infants, and Children [WIC], Supplemental Nutrition Assistance Program [SNAP], Temporary Assistance for Needy Families [TANF], or Children's Medicaid. For more information on documents that are acceptable as proof of adjunctive eligibility see the HTW website.

The HTW Application, HHS Form #H1867 is used to apply for HTW if the screening form indicates that a woman is likely to be determined eligible. Note: a HTW Screening Tool or HTW Application Form #H1867 must be maintained in the client record for all potentially eligible HTW individuals.

After ensuring that the application is completed and signed, the contractor must fax the application to the toll-free number included on the application to HHSC for processing. Verification of income, expenses, or adjunctive eligibility, identity, and citizenship must also be faxed with the application. Contractors must fax the application to the eligibility office even if all required documentation is not provided by the individual. The eligibility office will contact the person for any missing information. To minimize paperwork and the chance that verification will be lost, the documents should be photocopied to fit on one sheet, if possible. A woman's enrollment in HTW will be effective from the first day of the month the State receives her application for the program. For example, if a woman applies for HTW on January 20 and she is certified, her enrollment will be effective January 1.

Screening for FPP Eligibility

Contractors must determine FPP eligibility. To assess eligibility for FPP services, contractors must use either the Family and Social Services (FSS) Section eligibility form or an FSS Section-approved eligibility screening form substitute (e.g., in-house form, electronic/automated form, phone interview, etc.), that contains the required information for determining eligibility.

The eligibility assessment may be completed over the phone or in the office. The completed eligibility form must be maintained in the individual record, indicating the individual's poverty level and the co-pay amount he or she may be charged. An individual's eligibility must be assessed on an annual basis.

Re-Screening for HTW:

- An applicant must be re-screened at subsequent visits if her eligibility for HTW has not been determined after 45 calendar days from the application submission date.
- If the applicant seeks services within the 45 days from the application submission date, and the person has undetermined HTW eligibility, contractors are not required to re-screen for HTW.
- Applicants who were initially screened ineligible for HTW because of their citizenship or immigration status must be re-screened annually or when the individual reports a change in their citizenship or immigration status.
- If the applicant has been deemed ineligible for HTW, a copy of the denial letter must be maintained in the individual's record. Applicants who do not provide a copy of denial letter must be re-screened at subsequent visits.
- Individuals who refuse to apply for HTW must be re-screened at subsequent visits.

Please note the following:

- Medicaid-eligible individuals must never be charged a fee for services covered by Medicaid.
- HTW-eligible individuals must never be charged a fee for services covered by HTW.
- HHSC FPP-eligible individuals at or under 100 percent FPL must never be charged a fee for services covered by the program.
- Individuals must never be denied services because of inability to pay current fees or any fees owed. Signs indicating this policy should be visibly posted at contractor clinic sites.

Adjunctive Eligibility

An applicant is considered adjunctively (automatically) eligible for HHSC FPP services at an initial or renewal eligibility screening, if she/he is currently enrolled in one of the following programs:

- Children's Health Insurance Program (CHIP), Supplement Nutrition Assistance Program (SNAP),
- Temporary Assistance for Needy Families (TANF), and/or Special Supplemental Nutrition Program for Women, Infants, and Children (WIC).

The applicant must be able to provide proof of active enrollment in the adjunctively eligible program. Acceptable eligibility verification documentation may include:

PROGRAM	DOCUMENTATION
CHIP	*'Your Texas Benefits' card**
SNAP	*SNAP eligibility letter*
TANF	*TANF verification of certification letter*
WIC	*WIC verification of certification letter, printed WIC-approved shopping list, or recent WIC purchase receipt with remaining balance*

*NOTE: If the individual has a "Your Texas Benefits" Medicaid card, it can be used to document Medicaid eligibility.

To verify eligibility providers must call TMHP at 1-800-925-9126 or log on to TexMedConnect to check the member's Medicaid ID number (PCN).

If the applicant or the applicant's child (must be considered part of the household) is enrolled in the Children's Health Insurance Program (CHIP), she/he may be considered adjunctively eligible.

If the applicant's current enrollment status cannot be verified during the eligibility screening process, adjunctive eligibility would not be granted. Contractor would then determine eligibility according to usual protocols.

Calculation of Applicant's Federal Poverty Level Percentage

Household FPL Calculation

If a contractor collects a co-payment, the contractor must determine the applicant's exact household Federal Poverty Level (FPL) percentage. The steps to do so include:

- Determine the applicant's household size.
- Determine the applicant's total monthly income amount.
- Divide the applicant's **total monthly income** amount by the **maximum monthly income** amount at 100 percent FPL, for the appropriate **household size**.
- Multiply by 100 percent

The maximum monthly income amounts by household size are based on the Department of Health and Human Services federal poverty guidelines. The guidelines are subject to change around the beginning of each calendar year.

Example:

Applicant has a total monthly income of $2,093 and counts three (3) family members in the household.

Total Monthly Income		Maximum Monthly Income (Household Size of 3)						Actual Household FPL%
$2,093	÷	$1,702	=	1.22	x	100%	=	122% FPL

Date Eligibility Begins

An individual is eligible for services beginning the date the contractor determines the individual eligible for the program and signs the completed application.

Fees/Co-Payments

Client Fees/Co-pays

All FPP services provided at an HHSC FPP funded clinic, including non-reimbursable services, must be offered on a sliding fee scale. (See Example co-pay schedule posted online under the Forms section.)

Please note the following:

- Medicaid-eligible individuals must never be charged a fee for services covered by Medicaid.
- HTW-eligible individuals must never be charged a fee for services covered by HTW.
- HHSC FPP-eligible individuals at or under 100 percent FPL must never be charged a fee for services covered by the program.
- Individuals must never be denied services because of inability to pay current fees or any fees owed. Signs indicating this policy should be visibly posted at contractor clinic sites.

Co-Pay Guidelines:

If a contractor opts to charge a co-payment for services, a co-pay schedule must be developed and implemented with sufficient proportional increments so that inability to pay is never a barrier to service. Co-pay schedule requirements include:

- Individuals whose household income is at or below 100 percent of the FPL must *not* be charged a co-pay.
- Individuals between 101 percent and 250 percent FPL *may* be assessed a co-pay for FPP services, but it is not required. If an individual is charged a co-pay, the co-pay amount must be reflected on the individual's account.
- Individuals may not be charged an additional co-pay for services that are provided by referral.
- Individuals who are assessed a co-pay should be presented with the bill at the time of service.
- Contractors must maintain records regarding individual co-pays paid and any balance owed. Contractors must also have a system for aging accounts receivable. This system must be documented in the contractor's policy and procedures and must clearly indicate a timeframe for removing balances from an individual's account due to inability to pay.

- An example of a co-pay schedule is posted online in the Forms section. Contractors can adopt the example or develop their own. The co-pay schedule must have proportional FPL increments and co-pay amounts. The maximum co-pay amount must not exceed $30.00. The co-pay includes all prescriptions. If a contractor does not use the HHSC FPP example, the scale must be submitted to and approved by the HHSC FPP staff.
- The co-pay schedule must be updated when the revised Federal Poverty Income Guidelines are released.
- Contractors must have policies and procedures regarding co-pay collection, which must be approved by the contractor's Board of Directors.
- Services may be provided to individuals with third-party insurance if the confidentiality of the person is a concern or if the person's insurance deductible is 5 percent or greater of their monthly income.
- Co-payments collected by the contractor are considered program income and must be used to support the delivery of HHSC FPP services.

Other Fees

Individuals shall not be charged administrative fees for items such as processing and/or transfer of medical records, copies of immunization records, etc.

Contractors can bill individuals for services outside the scope of FPP reimbursable services if the service is provided at the individual's request and the person is made aware of his/her responsibility for paying the charges.

Continuation of Services

Contractors who have expended their awarded FPP funds are required to continue to serve their existing FPP clients.

If other funding sources are used to provide FPP services, the funds must be reported as non-HHSC funds on the monthly State Purchase Voucher and the quarterly Financial Status Report (FSR) (Form 269A).

CHAPTER 2: CLINICAL POLICY

This chapter describes the requirements and recommendations for FPP contractors pertaining to the delivery of direct clinical services to patients. In addition to the requirements and recommendations found within this section, contractors should develop protocols consistent with national evidence-based guidelines appropriate to the target population.

All providers must offer the following core family planning services:

- Contraceptive services (pregnancy prevention and birth spacing)
  - Intrauterine devices (IUDs), contraceptive implants, oral contraceptive pills, three-month (medroxyprogesterone) injections, sterilizations, etc.
- Pregnancy testing and counseling
- Health screenings
  - Cervical cancer screening (Pap smears, etc.)
  - Screening for hypertension, diabetes, and elevated cholesterol
- Preconception health (e.g., screening for obesity, smoking, and mental health)
- Sexually transmitted infection (STI) services
  - Chlamydia and gonorrhea screening and treatment
  - HIV screening

Covered Services

The FPP seeks to promote the general and reproductive health of Texas residents by providing safe and effective family planning services to men and women through 64 years of age who reside in Texas and meet program eligibility requirements.

The following services are covered under the FPP:

- Annual family planning and preventive healthcare visit;
- Pregnancy testing and counseling;
- Contraceptive services, all methods except elective abortion and emergency contraception, including necessary follow-up and surveillance;
- Certain health screening and diagnostic services, as indicated:
  - Screening, diagnosis, and treatment of Cervical Intraepithelial Neoplasia; diagnosis of cervical cancer
  - Breast cancer screening and diagnosis

- Screening and outpatient treatment for sexually transmitted diseases and infections (STD/STI)
- HIV screening
- Chlamydia and gonorrhea screening and treatment
- Syphilis screening and treatment
- Limited prenatal care services
- Recommended immunizations
- Screening for postpartum depression
- Diabetes screening
- Hypertension screening
- Screening for elevated cholesterol
- Preconception health (e.g. screening for obesity, smoking, and mental health)

Client Health Record and Documentation of Patient Encounters

Requirement for Documentation of Reproductive Health Services

All individuals should receive services related to reproductive health and/or contraception at least annually. Individuals using long-acting reversible contraception (intrauterine device, implantable hormonal contraceptive agent) and patients who have undergone permanent sterilization may continue to receive services under the program if they meet eligibility requirements.

The guiding principle of the FPP is to improve the reproductive health of women and men to ensure that every pregnancy is desired, and every baby is healthy. At each patient encounter, including encounters for treatment of other conditions (e.g., follow up of an abnormal Pap smear), the provider must educate the patient on how the service being provided relates to reproductive health or contraception, and this must be documented in the patient record.

For individuals who have undergone sterilization, and women who are post-menopausal or have had a hysterectomy, this counseling and documentation are not required when receiving covered services. This must be documented in the medical record at least annually.

Individual Health Records and Documentation of Encounters

Providers must ensure that a patient health record (medical record) is created for every individual who obtains clinical services.

All patient health records must be:

- A complete, legible, and accurate documentation of all clinical encounters, including those that take place by telephone;
- Written in ink without erasures or deletions; or documented in the Electronic Health Record (EHR) or Electronic Medical Record (EMR);
- Signed by the provider making the entry, including name of provider, provider title, and date for each entry.
  - Electronic signatures are allowable to document provider review of care.
  - Stamped signatures are not allowable.
- Readily accessible to ensure continuity of care and availability to patients; and
- Systematically organized to allow easy documentation and prompt retrieval of information.

The individual health record must include:

- Individual's identification and personal data, including financial eligibility;
- The individual's preferred language and method of communication;
- Individual's contact information, including the best way and alternate ways to reach the person, to ensure continuity of care, confidentiality, and compliance with HIPAA regulations;
- A person's problem list, updated as needed at each encounter, indicating significant illnesses and medical conditions;
- A complete medication list, including prescription and non-prescription medications, as well as dietary supplements, updated at each encounter;
- A complete listing of all medication allergies and adverse reactions, and other allergic reactions, displayed in a prominent place, and confirmed or updated at each encounter; if the person has no known allergies, this should be properly noted.
- Documentation of the individual's past medical history to include all serious illnesses, hospitalizations, surgical procedures, pertinent biopsies, accidents, exposures to blood products, and mental health history;
- A record or history of immunizations, including immunity to rubella based on a history of vaccine or documented serology testing;
- An individual's health risk survey and assessment, including past and current tobacco, alcohol, and substance use/abuse, domestic and/or intimate partner

violence and/or abuse (for any positive result, the individual must be offered referral to a family violence shelter in compliance with Texas Family Code, Chapter 91), occupational and environmental hazard exposure, environmental safety (e.g., seat belt use, car seat use, bicycle helmets, etc.), nutritional and physical activity assessment, and living arrangements, updated as appropriate at each encounter;

- At each encounter, an encounter-relevant history and physical examination pertinent to the person's reason for presentation, with appropriate laboratory and other studies as indicated;
- A plan of care, updated as appropriate, consistent with diagnoses and assessments, which in turn are consistent with clinical findings;
- Documentation of recommended follow-up care, scheduled return visit dates, and follow-up for missed appointments;
- Documentation of informed consent or refusal of services, to include at a minimum:
  - A general consent for treatment;
  - An individual's refusal of testing;
  - Sterilization consent form, if applicable;
  - A completed Texas Medical Disclosure Panel Consent form for any surgical services provided, if applicable;
  - For required or recommended services refused or declined by the person, documentation of the service offered, counseling provided, and the person's decision to decline.
  - Note the following special considerations for adolescent (17 years of age and younger) consent requirements, as required by the Texas Family Code, Chapter 32 and Chapter 151:
    - ◊ Adolescents are required to have consent from a parent or guardian prior to receiving certain medical services; proof of parental consent must be included in the minor patient's medical record when required.
    - ◊ Adolescents are not required to have parental consent to receive pregnancy-related services (including pregnancy testing), sexually transmitted disease/infection (STD/STI) and HIV testing, or STD/STI treatment.
- Documentation of client counseling and education, with attention to risks identified in the health risk assessment; and

- At every clinic visit, the record must be updated as appropriate, and the reason for the visit, any assessment made, and service provided must be documented.

Initial Clinical Visit

At the initial clinical visit, or an early subsequent visit, a comprehensive health history must be taken, to include, in addition to the elements required for the Individual Health Record above: (adapt as appropriate to the gender of the person)

- Reason for the visit and current health status;
- Review of systems with documentation of pertinent positives and negatives; and
- A reproductive health history.
  - For women, this includes menstrual history, complete obstetrical history, sexual activity history (including contraceptive practices, number and gender of partners, sexually transmitted infection/sexually transmitted disease [STI/STD] and HIV history and risk factors, whether currently sexually active), and reproductive life plan.
  - For men, this includes sexual activity history (including contraceptive practices, number and gender of partners, sexually transmitted infection/sexually transmitted disease [STI/STD] and HIV history and risk factors, whether currently sexually active), and reproductive life plan.
- For women: Cervical and breast cancer screening history, noting any abnormal results and treatment, and dates of most recent testing;
- For women: Other history of gynecological conditions;
- Other history of genital and/or urological conditions;
- Family health and genetic history.

At every subsequent visit, including the annual primary health care and problem visits, the record must be updated as appropriate, and the reason for the visit and current health status documented.

Annual Comprehensive Family Planning Visit, Physical Examination, and Testing

The annual family planning visit offers an excellent opportunity for providers to address issues of wellness and health risk reduction as well as addressing any current findings or patient concerns. The annual visit must include an update of the person's health record as described in the Individual Health Record section above,

as well as appropriate screening, assessment, counseling, and immunizations based on the individual's age, risk factors, preferences, and concerns.

All individuals must undergo a physical examination annually as part of the family planning visit. This can be deferred to a later date if the person's current history and health status do not suggest issues requiring more urgent examination. However, the annual physical examination should not be deferred longer than 6 months, unless the clinician identifies a compelling reason for extended deferral. Such reason must be documented in the individual's record. Any breast or pelvic examination should be performed only with the consent of the person. Individuals must be offered a suitable method of contraception, such as oral contraceptives, without delay even if the physical examination is put off temporarily or an otherwise asymptomatic individual decline any or all components of the examination.

- It is recommended that the family planning visit include all the following components, at least annually, in addition to any other appropriate elements as suggested by history and presenting signs and symptoms (all findings, including tests, results, and the individual's notification of results, should be documented in the medical record, as well as an individual's refusal or other reason for not testing or performing a specified part of the examination):
  - Measurement of height, weight, and blood pressure (BP) screening for hypertension; and
  - Calculation of body mass index (BMI) with assessment for underweight, overweight, or obesity, with counseling (if indicated) on achieving and maintaining a healthy body weight. (An adult BMI calculator and a BMI calculator for children and teens are available from the Centers for Disease Control and Prevention.)

For females:

- Clinical breast examination, breast cancer risk assessment, and breast cancer screening as appropriate based on person's age, risk, and preferences;
- Counseling on breast awareness and advice to report any symptom or sign that is concerning to the individual;
- Screening for cervical cancer beginning at 21 years of age, regardless of sexual history, and continuing as indicated based on the individual's age, prior test results, and treatment history; and

- Pelvic examination (for all consenting individuals 21 years and older; only if indicated by the medical history in consenting individuals less than 21 years of age) to include the following elements:
- Visual examination of the external genitalia, vaginal introitus, urethral meatus, and perianal area;
- Speculum examination of the cervix and vagina;
- Bimanual examination of the cervix, uterus, and adnexa; and when indicated, rectovaginal examination.

For males:

- Visual and manual examination of the external genitalia (scrotum, penis, and testicles) and visual inspection of the perianal area;
- Assessment for hernia;
- Palpation of the prostate as indicated by history and person's age; and
- Advice on testicular awareness and recommendation to report any symptom or sign that is concerning to the person.
- Other examination as indicated by history, signs and symptoms, and the individual's concerns (e.g., thyroid, heart, lungs, abdomen, etc.):
- Diabetes screening as appropriate for age and risk factors;
- Sexually transmitted infections;
- Pregnancy testing, available on-site (If the pregnancy test is positive, the person must be given information on good health practices during pregnancy and given or referred for appropriate physical evaluation and initiation of prenatal care, preferably within 15 days.);
- Rubella immunity testing in women of reproductive age if the status cannot be determined by history or previous testing;
- Cholesterol and/or serum lipid testing;
- Thyroid stimulating hormone;
- Immunizations as indicated (Healthcare providers can voluntarily participate in the Texas Department of State Health Services (DSHS) Adult Safety Net (ASN) vaccine program, which provides vaccines at no cost); and
- Other testing if indicated.
- Appropriate family planning counseling and treatment;
- Healthy lifestyle interventions and counseling as indicated based on age, risk factors, and client interest and receptiveness.

Counseling and Education

All individuals must receive accurate person-centered education and counseling in their preferred language, presented in a way they are able to understand and to demonstrate their understanding, and documented in the medical record. The intent of individual education is to enable the person to understand the range of available services and how to access them, to make informed decisions about family planning, to reduce personal health risk, and to understand the importance of recommended tests, health promotion, and disease prevention strategies.

Specific clinical policies must be in place to address counseling and other services provided to adolescents 17 years of age and younger, to include the following, at a minimum:

- Counseling of adolescents must include the following topics:
  - All medically approved methods of contraception, including abstinence;
  - Prevention of STD/STIs and HIV;
  - Domestic, partner, dating, and family violence and the offer of assistance as needed; and
  - Recognition and avoidance of sexual coercion.
- Counseling and clinical services to adolescents must be expedited so that appointments are made available as soon as possible.
- Adolescents must be assured that their privacy and confidentiality will be protected within the parameters of applicable law, including the Health Insurance Portability and Accountability Act (HIPAA), Texas Family Code, Chapter 32, and Section II Chapter 2 (Consent) of this policy manual.

Details of appropriate educational interventions are included in each section of this clinical policy manual. In addition, links are provided to information of use to individuals and educators at the end of most sections.

Requirements for Policies to Ensure Appropriate Follow-up and Continuity of Care

Providers must develop and maintain policies and procedures to ensure proper timely follow-up and continuity of care, to include, at a minimum:

- Tracking pending tests until results are reviewed by provider and the individual is notified of results and recommended follow-up;
- Documentation of all tests and results in the Individual Health Record;

- A mechanism to inform individuals promptly of test results that protects the person's privacy and confidentiality while supporting and promoting timely, appropriate follow-up;
- A mechanism to track individual compliance with recommended follow-up care, schedule return visits, and follow-up on missed appointments; and
- A process to ensure compliance with all applicable state and local laws for disease reporting.

Before a person is considered lost to follow-up, the contractor must make at least three documented separate attempts to contact the person, using an accelerated protocol, where subsequent attempts involve a more intensive effort to contact the person. An example might be a telephone call on the first attempt, a letter by regular mail on the second, and a certified letter on the third. Providers should develop processes that are adapted to the circumstances of the population they serve, and adapt their usual processes based on their knowledge of the circumstances and preferences of the individual they are attempting to contact.

Problem Visits

For all problem visits, the following elements must be documented in the medical record:

- Reason for the visit
- Appropriate interval medical history and focused history relevant to the problem reported
- Relevant physical examination and testing as indicated, as well as an assessment and treatment prescribed

Referrals

When a person is referred to another provider of services for consultation or continuation of care, the chart must reflect a record of the purpose for the referral, the name of the provider consulted or referred to, counseling of the person regarding the purpose of the referral and answering any questions the person has about the referral. Pertinent individual information and appropriate portions of the medical record must be provided to the referral clinician, and this must also be documented in the medical record. The results of the consultation or referral must be followed up on and documented in the medical record.

When services covered under the FPP are to be provided by referral, the contractor must establish a written agreement with a referral resource for the provision of

services and reimbursement of costs and ensure that the patient is not charged by the referral resource for these services.

Contractors must maintain a written policy reflecting these requirements for referral activities.

Prescriptive Authority Agreements

When services are provided by Advanced Practice Registered Nurse(s) and/or Physician Assistant(s), it is the responsibility of the contractor to ensure that a properly executed prescriptive authority agreement (PAA), as required by Texas Administrative Code Title 22, Part 9, Chapter 193, is in place for each such provider. This is true whether the provider is employed by the contractor or is providing services by subcontract with or referral by the contractor. The PAA must meet all the requirements delineated in the Texas Occupations Code, Chapter 157, including, but not limited to, the following minimum criteria:

- Be in writing and signed and dated by the parties to the agreement;
- Include the name, address, and all professional license numbers of all parties to the agreement;
- State the nature of the practice, practice locations, or practice settings;
- Identify the types or categories of drugs or devices that may be prescribed, or the types or categories of drugs or devices that may not be prescribed;
- Provide a general plan for addressing consultation and referral;
- Provide a plan for addressing patient emergencies;
- Describe the general process for communication and sharing of information between the physician and the advanced practice registered nurse or physician assistant to whom the physician has delegated prescriptive authority related to the care and treatment of individuals;
- If alternate physician supervision is to be utilized, designate one or more alternate physicians who may:
  - Provide appropriate supervision on a temporary basis in accordance with the requirements established by the prescriptive authority agreement and the requirements of this subchapter; and
  - Participate in the prescriptive authority quality assurance and improvement plan meetings required under this section; and
- Describe a prescriptive authority quality assurance and improvement plan and specify methods for documenting the implementation of the plan that includes the following:

- Chart review, with the number of charts to be reviewed determined by the physician and advanced practice registered nurse or physician assistant; and
- Periodic face-to-face meetings between the advanced practice registered nurse or physician assistant and the physician at a location determined by the physician and the advanced practice registered nurse or physician assistant.

The PAA need not describe the exact steps that an advanced practice registered nurse or physician assistant must take with respect to each specific condition, disease, or symptom. The PAA and any amendments must be reviewed at least annually, dated, and signed by the parties to the agreement. A copy of the current PAA must be maintained on-site where the advanced practice registered nurse or physician assistant provides care.

Standing Delegation Orders

When services are provided by unlicensed and licensed personnel, other than advanced practice nurses or physician assistants, whose duties include actions or procedures for a population with specific diseases, disorders, health problems or sets of symptoms, the clinic must have written standing delegation orders (SDOs) in place. SDOs are distinct from specific orders written for a particular individual. SDOs are instructions, orders, rules, regulations or procedures that specify under what set of conditions and circumstances actions should be instituted. The SDOs delineate under what set of conditions and circumstances an RN, LVN, or non-licensed healthcare provider (NLHP) may initiate actions or tasks in the clinical setting and provide authority for use with individuals when a physician or advance practice provider is not on the premises, and/or prior to being examined or evaluated by a physician or advanced practice provider. Example: SDO for assessment of Blood Pressure/Blood Sugar which includes an RN, LVN or NLHP that will perform the task, the steps to complete the task, the normal/abnormal range, and the process of reporting abnormal values.

Other applicable SDOs when a physician is not present on-site may include, but are not limited to:

- obtaining a personal and medical history;
- performing an appropriate physical exam and the recording of physical findings;
- initiating/performing laboratory procedures;

- administering or providing drugs ordered by voice communication with the authorizing physician;
- providing pre-signed prescriptions for:
  - oral contraceptives;
  - diaphragms;
  - contraceptive creams and jellies;
  - topical anti-infective for vaginal use; or
  - antibiotic drugs for treatment of STI/STDs.
- handling medical emergencies – to include on-site management as well as possible transfer of the individual;
- giving immunizations; or
- performing pregnancy testing.

The SDOs must be reviewed, signed, and dated by the supervising physician who is responsible for the delivery of medical care covered by the orders and other appropriate staff, at least annually and maintained on- site.

References

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American College of Obstetricians and Gynecologists (2012). Committee opinion 534: Well-woman visit. *Obstet Gynecol* 120: 421-424. Available at http://www.acog.org/Resources_And_Publications/Committee_Opinions/Committee_on_Gynecologic_Practice/Well-Woman_Visit

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Affairs, 2015. *MMWR* 65(9); 231-234. Available at https://www.cdc.gov/mmwr/volumes/65/wr/mm6509a3.htm

Centers for Disease Control and Prevention. Immunization schedules website. Available at (http://www.cdc.gov/vaccines/schedules/

Family Planning and Contraceptive Services

Reproductive Life Plan

Providers should encourage all individuals to develop a reproductive life plan, which is an outline of each person's immediate and future plans for having children. Questions such as the following can be useful in helping individuals to develop the plan:

- Do you have children now?
- Do you desire to have (more) children?
- How many children would you like to have and when?

Of course, providers and individuals should understand that such plans can change with time. Providers should take the individual's stated plan into account in counseling on contraceptive and family planning services.

- If the person is sexually active and does not desire pregnancy, offer contraceptive services.
- Provide pregnancy testing and counseling to any female who may be pregnant or who requests such testing. Initiate or provide referral for prenatal services if positive.
- If pregnancy is currently desired and the woman is not pregnant, offer services to help her and her partner to achieve a safe and healthy pregnancy.

Contraceptive Counseling and Education

At each encounter for services, individuals must receive patient-centered counseling and education to enable them to make informed decisions about family planning, including information on preventing STD/STIs and HIV, the results of the physical examination and other testing, method-specific counseling as described below, and other counseling as indicated by the history and clinical evaluation. Counseling should include the importance of developing a reproductive life plan and information about reproductive health, family planning methods and services, and obtaining preconception health services, as appropriate.

Providers must offer individuals a wide array of contraceptive options appropriate for the person's health status and reproductive plan. A 6-step approach that seeks to engage the person in the decision-making process while addressing individual personal and cultural preferences will improve individual satisfaction and the likelihood that the selected method will be used correctly and consistently.

- Establish and maintain rapport with the person. Some ways to do this include:
  - Ask open-ended questions.
  - Ensure confidentiality and privacy and explain how confidential information may be used.
  - Listen to and observe the person.
  - Encourage questions and provide culturally sensitive answers that demonstrate knowledge of the subject matter in language the person understands.
- Obtain social and clinical information from the person to include the following:
  - Health history;
  - Current reproductive life plan;
  - Contraceptive experience and possible preferences; and
  - Assessment of sexual health:
    - ◊ Past and current contraceptive practices;
    - ◊ Partner history (e.g., number, gender, whether concurrently monogamous);
    - ◊ Current and past STD/STI prevention (e.g., limiting partners, use of condoms, barriers to condom use, consistency of use); and
    - ◊ Prior treatment for and possible exposure to STD/STIs.
- Work interactively with the person to choose the most appropriate contraceptive method for the individual.
  - Educate the person about all contraceptive methods that are safe and appropriate for that individual. An online patient decision support tool is available from the Association of Reproductive Health Professionals.
  - Providers should counsel individuals on the relative effectiveness of methods, correct use of methods, potential non-contraceptive benefits (e.g., reduced risk of iron-deficiency anemia with combination hormonal contraceptives), and method side effects, working with the individual or couple to select the method that best meets their needs and wishes.

- Individuals should be informed that contraceptive methods other than condoms provide no protection from STD/STIs, including HIV; and that condoms used correctly and consistently do help to reduce the risk of STD/STIs, including HIV.
- Help the person to identify barriers to correct contraceptive method use and develop solutions to overcome barriers.

- Perform a physical evaluation appropriate to the method chosen, when warranted. In most cases, no physical examination or laboratory testing is necessary prior to initiating a contraceptive method.
  - Blood pressure should be recorded prior to starting combination hormonal contraception.
    - ◊ Current pregnancy status should be determined at the time of service for any woman receiving contraceptive services, but routine pregnancy testing is not necessary if it is possible to be reasonably certain that she is not pregnant. A provider may be reasonably certain that a woman is not currently pregnant if she has no signs or symptoms of pregnancy (either intrauterine or ectopic) and meets at least one of the following criteria:
    - ◊ < 7 days since the start of a normal menses;
    - ◊ No sexual intercourse since the beginning of the last normal menses;
    - ◊ Has been using a reliable method of contraception correctly and consistently;
    - ◊ < 7 days since a spontaneous or induced abortion;
    - ◊ < 4 weeks postpartum; or
    - ◊ < 6 months postpartum, amenorrheic since delivery, and exclusively or almost exclusively breast feeding (at least 85 percent of infant feedings are breast feedings).
  - Weight assessment is not necessary before initiating a contraceptive method because obesity alone is not a contraindication to any method. However, a baseline weight measurement may aid in assessing the possible effect of a chosen method on weight change.
  - Certain tests and components of the physical examination may provide logistical, economic or emotional barriers to contraceptive access or acceptance for some women. In most cases, many of these interventions can be safely delayed or avoided altogether if necessary, to enable a healthy individual to initiate an appropriate and preferred method (although there may be other healthcare-related indications for the

interventions). The following tests and examinations are not necessary prior to initiating a contraceptive method:
  - ◊ Pelvic examination, except when fitting a diaphragm or inserting an IUD;
  - ◊ Cervical, breast, or other cancer screening;
  - ◊ HIV screening;
  - ◊ Laboratory testing for hemoglobin, glucose, lipid, or liver enzyme levels; or for thrombogenic mutations; or
  - ◊ Any physical examination prior to distributing condoms.

- Once a method of contraception is selected, the provider should provide counseling on correct and consistent use, assist the individual to develop a plan for correct use and follow-up, and confirm the person's understanding. Certain considerations may increase the likelihood of correct and consistent use.
  - Ideally, the method should be dispensed on-site (note on-site pharmacy requirements for contractors in the section below on Specific method access requirements for contractors) and started at the time of the visit (rather than waiting for the next menses), if the provider can be reasonably certain the woman is not pregnant (see item 4.b above for criteria to determine with reasonable certainty that a woman is not currently pregnant).
  - Multiple cycles (ideally a full year's supply) of oral contraceptive pills, the patch, or the ring should be prescribed or provided to reduce the number of return visits necessary.
  - Make condoms available easily.
    - ◊ Note: All FPP contractors must make barrier methods and spermicides available on-site.
  - If the individual's chosen method is not available on-site or immediately, provide another method on the day of the visit to be used until the chosen method can be started.
- Finally, help the person develop a plan for correct and consistent use of the chosen method and provide a plan for follow-up.
  - Explore possible reasons for incorrect or inconsistent use and help develop strategies to deal with these. For example:
    - ◊ Suggest a daily text message or a sign on the bathroom mirror to routinize daily pill taking.
    - ◊ Discuss ways to ensure timely return for injections.

- Discuss side effects, a common reason for method discontinuation, and ways to deal with these.
- Create a follow-up plan with the person, taking into account the person's individual needs and perceived risk of method lapse or discontinuation.
- Confirm the person's understanding of the information given and document this in the medical record.
  - ◊ The teach-back method, in which the individual demonstrates understanding of the information by repeating back the messages received, is a good way to confirm understanding and to increase retention of the information received.
  - ◊ Provide counseling with teach-back of the following topics, at a minimum:
    - Real-world method effectiveness;
    - Correct method use and common side effects;
    - Back-up contraceptive methods, including issues related to discontinuation of the chosen method;
    - Whether or not the method protects against STD/STIs;
    - Signs of rare, but serious, complications, and what to do if any of these signs occurs;
    - How to seek urgent or emergency care, including a 24-hour emergency telephone number; and
    - When to return for follow-up.

Relative Method Effectiveness

The following contraceptive methods are approved for reimbursement under FPP.

It is the contractor's responsibility to ensure that all contraceptive methods approved for reimbursement by the FPP are made available at no additional charge to the individual.

Relative method effectiveness (range of effectiveness for 100 women using the method for 1 year) is indicated in parentheses, if reported values are available. Actual effectiveness depends on correctness and consistency of use. Higher rates of effectiveness are seen with perfect use; real-world effectiveness is generally reflected in the lower end of the effectiveness range.

- Extremely effective (~99 percent)
  - Total sexual abstinence;
  - Contraceptive implant;

  - Intrauterine device; and
  - Male or female sterilization.
- Less effective (ranges of effectiveness are shown where the source used provides a range or multiple sources provide differing rates or ranges):
  - Lactational amenorrhea (98-99 percent; must be < 6 months postpartum, amenorrheic, and providing 85-100 percent of infant feedings as breast feedings)
  - Progestin injection (Depo-Provera, 94-97 percent)
  - Hormonal contraceptive pills (91-92 percent)
  - Hormonal contraceptive patch (91-92 percent)
  - Vaginal ring (91-92 percent)
  - Diaphragm (82-88 percent)
  - Male condom (82-85 percent)
  - Female condom (79 percent)
  - Withdrawal ("pulling out," 78-82 percent)
  - Cervical cap (71-86 percent)
  - Fertility awareness ("rhythm," 75-76 percent)
  - Spermicide (71-72 percent)
  - Sponge (68-88 percent, more effective in parous women)

Long-Acting Reversible Contraceptive (LARC) Methods

Because of their safety, reversibility, ease of use, and very high real-world effectiveness, providers are encouraged to make long-acting reversible contraceptive (LARC) agents and devices (i.e., the intrauterine device and the subdermal contraceptive implant) available to all who are candidates for their use. See the web page Long-Acting Reversible Contraception Program from the American Congress of Obstetricians and Gynecologists for information and resources on the use of LARCs.

For more information on implementing a program to provide LARCs, see the Texas LARC Toolkit on the Healthy Texas Women website.

Consent for Sterilization

For individuals who choose male or female sterilization, 2 consent forms are required to be signed by the person after counseling on method-specific risks and benefits is provided and all the person's questions have been answered:

- The Sterilization Consent Form must be signed by the person at least 30 days and not more than 180 days prior to the procedure. An exception is

made if the person undergoes emergency abdominal surgery or preterm birth, in which case, the form must be signed at least 72 hours before the sterilization procedure (and at least 30 days prior to the expected date of delivery if preterm birth is the reason for the exception).

- A Texas Medical Disclosure Panel Consent for the surgical procedure by which sterilization will be performed must be signed by the person after full disclosure of the risks and possible benefits is provided and all the patient's questions are answered.

Specific Method Access Requirements for Contractors

The following methods must be made available:

- LARC methods (i.e., the intrauterine device and the subdermal contraceptive implant) must be available on-site or by referral.
- Male and female sterilization must be made available, subject to program funding stipulations.
- All contractors must make injectable hormonal contraceptive agents, male and female condoms, spermicides, diaphragm, contraceptive sponge, cervical cap, and counseling and education on sexual abstinence available on-site.
- Contractors who are subject to the requirement to maintain a class D pharmacy must also make oral and transdermal hormonal contraceptive agents or vaginal hormonal contraceptive ring available on-site.

The table below outlines the requirements for on-site availability of contraceptive methods and anti-infective agents for FPP contractors:

	On-site Availability Required
Contraceptive Method or Anti-infective Agent	Class D Pharmacy
Anti-infective agents for treatment of STD/STIs	•
Barrier methods and spermicides	•
Injectable hormonal contraceptives	•
Oral contraceptives	•

Transdermal hormonal contraceptive (patch) and/or vaginal hormonal contraceptive (ring)	•
Sexual abstinence education and counseling	•

Contraceptive Methods that May Be Provided by Referral

If the clinicians associated with a FPP contractor do not provide covered contraceptive services that require a special level of training or expertise (e.g., sterilization, intrauterine device, hormonal implant, and diaphragm fitting), these services may be offered through a vendor agreement to another provider at no additional cost to the individual. FPP contract clinics that offer such services by vendor agreement must have a written agreement with the vendor providing the method(s) to offer the method or service under this condition.

Note:

- Abortion is not considered a method of family planning and no state funds appropriated to the department shall be used to pay the direct or indirect costs (including overhead, rent, phones and utilities) of abortion procedures provided by contractors.
- Emergency contraceptive pills (EC or ECP) and related provider services are not reimbursable under the FPP.

References

- Centers for Disease Control and Prevention (2014). Providing quality family planning services. *MMWR* 63(4). Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6304a1.htm (web) http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf (PDF)
- Centers for Disease Control and Prevention (2016). Update: Providing quality family planning services - Recommendations from CDC and the U.S. Office of Population Affairs, 2015. *MMWR* 65(9); 231-234. Available at https://www.cdc.gov/mmwr/volumes/65/wr/mm6509a3.htm
- Centers for Disease Control and Prevention. U.S. selected practice recommendations for contraceptive use, 2016. *MMWR* 65(No. 4). Available at https://www.cdc.gov/reproductivehealth/contraception/mmwr/spr/summary.html (web) https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6504.pdf

(PDF)

Resources for Patients and Educators

- Association of Reproductive Health Professionals. Method Match. Online decision support tool to help patients compare and select from different methods of contraception; includes information on relative effectiveness of methods. Available at http://www.arhp.org/methodmatch/

Resources for Providers

- American Congress of Obstetricians and Gynecologists. Long-acting reversible contraception program web page. Provides information, clinical guidance, and educational materials on Long-acting reversible contraceptives [LARCs]. Available at https://www.acog.org/About_ACOG/ACOG_Departments/Long_Acting_Reversible_Contraception

Preconception Services

The goal of preconception care is optimizing the health of every woman to lay the foundation for the best possible outcome of every pregnancy. Because almost half of all pregnancies in the United States are unplanned, and most pregnancies occur in women who did not have a specific preconception care visit prior to becoming pregnant, providers should keep preconception care in mind at every encounter with a woman of childbearing potential.

Good preconception care incorporates all components of general health care as described elsewhere in this manual. Attention should be paid to the following components:

- Optimization of known chronic medical conditions, such as diabetes, hypertension, thyroid disease, epilepsy, asthma, etc.
  - A normal hemoglobin A1c prior to and early in pregnancy can substantially reduce the risk of birth defects in the offspring of mothers with Type 1 and Type 2 diabetes.
  - Women with hyperthyroidism or hypothyroidism should be treated as necessary to ensure that they are euthyroid prior to and during pregnancy to reduce the risk of miscarriage and preterm birth.
  - Women with a history of phenylketonuria should be counseled on the need to follow a low-phenylalanine diet before and during pregnancy to

reduce the risk of birth defects and serious developmental delay in the offspring.

- Screening as indicated for any conditions that may be undiagnosed;
- Confirming that immunizations are current;
- Medications (prescription and nonprescription) and potential radiation exposure in early pregnancy:
  - In general, the lowest effective dose of necessary medications is preferred, but individuals should be cautioned against discontinuing or changing medications without first consulting their doctor, because an untreated or incompletely treated medical condition may pose greater risk to the fetus and mother than the medication prescribed.
  - Some known teratogenic medications include warfarin, valproic acid, carbamazepine, isotretinoin, and angiotensin-converting enzyme inhibitors.
  - For more individual and provider information on risk associated with specific exposures to medications and other environmental factors, consult the web site of the Organization of Teratology Information Specialists.
- Prevention of STD/STIs;
- Nutrition and food insecurity;
- Occupational and environmental exposures to health risks and teratogens;
- Tobacco and substance use, other high-risk behaviors;
- Family medical history and genetic risk;
- Domestic, intimate, and partner violence;
- Social issues, such as homelessness; and
- Mental health.

References

- American Academy of Pediatrics/American College of Obstetricians and Gynecologists. *Guidelines for Perinatal Care 7th Ed*. (2012). Ch. 5, pp. 95-106.
- American College of Obstetricians and Gynecologists. Committee opinion 313: The importance of preconception care in the continuum of women's health care. Obstet Gynecol (2005). 106: 665-666. Available at http://www.acog.org/Resources_And_Publications/~/link.aspx?_id=75AD1BF47A76489F8E719EA5E3F22797&_z=z

- Centers for Disease Control and Prevention. Recommendations to improve preconception health and health care – United States. *MMWR* (2006). 55(RR06): 1-23. Available at http://www.cdc.gov/mmWR/PDF/rr/rr5506.pdf
- Organization of Teratology Information Specialists. Mother to Baby: Medications & more during pregnancy & breastfeeding. Available at http://mothertobaby.org/fact-sheets-parent/ (provides information for patients and health care providers on teratogenic risk of drugs and other exposures in pregnancy)

Resources for Patients and Providers

- American Society for Reproductive Medicine. http://www.reproductivefacts.org/ (information for patients on a variety of topics related to fertility and infertility)
- Centers for Disease Control and Prevention. Content of care for women website. Available at http://www.cdc.gov/preconception/careforwomen/index.html
- Centers for Disease Control and Prevention. Clinical content of care for men website. Available at http://www.cdc.gov/preconception/careformen/index.html
- Centers for Disease Control and Prevention. Preconception health and health care web site. Contains links to resources for patients, providers, and patient educators on planning for a healthy pregnancy. Available at http://www.cdc.gov/preconception/index.html

Cervical Cancer Screening

Note that the summary of cited guideline recommendations provided in this section reflect the ages of eligibility for the FPP, and do not include guideline recommendations for individuals outside this range.

In writing this summary, guidelines from a variety of medical specialty organizations and US government agencies were reviewed. Where slight divergence was found among guidelines from different organizations, an attempt was made to synthesize the recommendations so that all recommendations are represented cohesively in the summary below.

The majority of cases of cervical cancer occur in women who have never had screening or have had inadequate screening. It is estimated that half of women who receive a diagnosis of cervical cancer have never had cervical cytology testing,

and an additional 10 percent have not had screening in the 5 years prior to the diagnosis of cancer. Providers are encouraged to implement and participate in programs aimed at increasing the percentage of women in their communities who receive indicated cervical cancer screening.

General Considerations

Cervical cancer screening should begin at 21 years of age. Except for women who are infected with HIV or otherwise immunocompromised, screening should not be performed prior to age 21.

Women with the following risk factors are at higher risk and may require more frequent screening than described in this policy manual, which is intended for women of average risk:

- Women with HIV infection or other reason for immunocompromise (e.g., history of solid organ transplant)
- History of in utero exposure to diethylstilbesterol
- Prior treatment for CIN 2, CIN 3, or cervical cancer.

Either liquid-based or conventional (PAP smear) methods of cervical cytology are acceptable.

When human papillomavirus (HPV) testing is performed, it should include testing to detect only those HPV genotypes with known carcinogenic potential, so-called high-risk HPV genotypes. Testing for low-risk genotypes, those without demonstrated carcinogenic potential, should not be performed. References to HPV testing in the remainder of this topic section are for high-risk HPV only.

Screening guidelines should be applied to women who have received the HPV vaccine in the same way as for women who have not received the vaccine.

Screening Frequency and Response to Abnormal Findings

Routine annual cervical cancer screening is not appropriate for women of average risk in any age group. Women 21-29 years of age should undergo screening every 3 years by cervical cytology testing alone, with reflex human papillomavirus (HPV) testing when cytology reveals atypical squamous cells of undetermined significance (ASCUS). Co-testing (cervical cytology combined with routine HPV testing) should not be performed in women younger than 30 years of age.

For women 25-29 years of age, the FDA-approved primary HPV screening test may be considered as an alternative to cytology-based screening, although cytology

alone with reflex HPV testing when cytology reveals ASCUS is recommended by major professional society guidelines. If the primary HPV test is to be used for screening, it should be done according to interim guidance provided by the American Society for Colposcopy and Cervical Pathology and the Society of Gynecologic Oncology.

For women 30-64 years of age, published guidelines recommend screening by any of three methods:

- Co-testing (combined cervical cytology and HPV testing) every 5 years
- Cervical cytology testing alone, with reflex HPV testing when cytology reveals ASCUS, every 3 years
- Screening with the FDA-approved primary HPV screening test every 5 years; if the primary HPV test is to be used for screening, it should be done according to interim guidance provided by the American Society for Colposcopy and Cervical Pathology and the Society of Gynecologic Oncology.

It is reasonable to perform annual cervical cytology testing in women with in utero exposure to diethylstilbestrol. For any individual with an abnormal result, further testing and follow-up should be dictated by findings, diagnosis, and current evidence-based guidelines, such as that of the American Society for Colposcopy and Cervical Pathology.

Discontinuation of Screening

For women in the FPP age group, screening should be discontinued after a hysterectomy with removal of the cervix in individuals with no prior history of CIN 2 or greater.

References

American Society for Colposcopy and Cervical Pathology (2013). Consensus guidelines for managing abnormal cervical cancer screens & CIN/AIS. Available at http://www.asccp.org/asccp-guidelines

Huh, W. K., Ault, K. A., Chelmow, D., Davey, D. D., Goulart, R. A., Garcia, F. A., Einstein, M. H. (2015). Use of primary high-risk human papillomavirus testing for cervical cancer screening: Interim clinical guidance. *Gynecol Oncol, 136*(2), 178-182.

Practice Bulletin No. 168: Cervical cancer screening and prevention. (2016). *Obstet Gynecol, 128*(4), e111-e130.

US Department of Health and Human Services Panel on opportunistic infections in HIV-infected adults and adolescents. Guidelines for the prevention and treatment of opportunistic infections in HIV-infected adults and adolescents: recommendations from the Centers for Disease Control and prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. Available at https://aidsinfo.nih.gov/guidelines/html/4/adult-and-adolescent-opportunistic-infection/0

US Preventive Services Task Force, Curry, S. J., Krist, A. H., Owens, D. K., Barry, M. J., Caughey, A. B., Wong, J. B. (2018). Screening for cervical cancer: US Preventive Services Task Force Recommendation Statement. *JAMA, 320*(7), 674-686.

Breast Cancer Screening

Note that the summary of cited guideline recommendations provided in this section reflect the ages of eligibility for the FPP, and do not include guideline recommendations for individuals outside this range.

Risk Screening and Individual Counseling

All females should have an assessment of their risk for breast cancer, updated periodically, to include the individual's age and ethnicity, personal and family history of breast cancer, other relevant genetic predisposition to breast cancer, and any history of chest radiation (particularly before age 30). A risk calculator for the individual 5-year risk of developing breast cancer for women 35 years of age and older is available from the National Cancer Institute.

All individuals should be counseled on breast awareness and advised to be familiar with their breasts and to report any changes (such as a mass, lump, thickening, or nipple discharge) promptly.

Screening Frequency

The following considerations* apply to women 40 years of age and older who do not have a preexisting breast cancer or other high-risk breast lesion and who do not have a known underlying genetic mutation (such as a BRCA1 or 2 mutation, or other familial breast cancer syndrome) or a history of chest radiation at an early age:

- All individuals 50-64 years of age should be offered screening mammography every other year.

- The decision for screening mammography in women 40-49 years of age should be individualized:
  - While screening mammography may reduce breast cancer-related deaths in this population, the number of deaths prevented is less than in older populations and the number of false-positive mammography results and negative biopsies is higher.
  - Women who undergo regular screening mammography face a risk of the diagnosis and subsequent treatment of breast cancer that would not otherwise have become apparent or threatened their health during their lifetime (overtreatment).
  - Women with a first-degree relative (parent, sibling, or child) with breast cancer are at increased risk and may benefit more from screening in their 40s than average-risk women.
  - Women who place a higher value on the potential benefits of screening than on the potential harms may choose, and should be allowed, to undergo biennial screening beginning sometime between age 40 and 49.
- Digital mammography combined with breast tomosynthesis may improve the rate of cancer detection and decrease call-back rates in some women, although this practice may increase the total radiation dose.
- There is insufficient evidence to assess the balance of benefits and harms for the use of breast ultrasonography, magnetic resonance imaging, or other methods of adjunctive screening in women with dense breasts identified on an otherwise negative screening mammogram.

More frequent or earlier screening mammography may be considered in women with increased or uncertain individual breast cancer risk and in other circumstances where the balance of potential benefits and harms of screening is felt to justify it.

*Note that the recommendations for frequency of mammography screening described above come from the US Preventive Services Task Force Recommendation Statement on Screening for Breast Cancer. The National Comprehensive Cancer Network recommends annual screening mammography be offered to all asymptomatic women 40 years of age and older. Links to both guidelines are provided in the References section immediately below.

Follow-up and Referral for Treatment

Any individual with an abnormality identified on screening or a specific breast complaint (including, but not limited to, a mass, lump, thickening, or nipple discharge) should be evaluated as indicated in a timely manner. Providers should

have procedures in place to ensure appropriate individual education and counseling, referral for further evaluation (including additional testing and biopsy) when indicated, communication and coordination with the person and other providers, and proper follow-up through the conclusion of the case.

For persons who require referral for services beyond those available through the contracted provider, contractors are encouraged, whenever possible, to refer to a HHSC Breast and Cervical Cancer Services (BCCS) contractor. Information is available at https://hhs.texas.gov/Doing-Business-HHS/Provider-Portals/Health-Services-Providers/Womens-Health-Services/Breast-Cervical-Cancer-Services

Eligible individuals in need of treatment for biopsy-proven breast cancer may apply for coverage under the Medicaid for Breast and Cervical Cancer Program. Information is available at https://hhs.texas.gov/doing-business-hhs/provider-portals/health-services-providers/womens-health-services/breast-cervical-cancer-services/breast-cervical-cancer-treatment-information

References

- Siu, AL. Screening for breast cancer: US Preventive Services Task Force Recommendation Statement. *Ann Intern Med.* 2016;164(4):279-296. Available at http://annals.org/article.aspx?articleid=2480757 (web)
- National Comprehensive Cancer Network. (2018). NCCN clinical practice guidelines in oncology: Breast cancer screening and diagnosis. Version 2.2018. Available at https://www.nccn.org/professionals/physician_gls/f_guidelines.asp#breast_screening

Additional Reading

- National Comprehensive Cancer Network. (2018). NCCN clinical practice guidelines in oncology: Breast cancer risk reduction. Version 2.2018. Available at https://www.nccn.org/professionals/physician_gls/f_guidelines.asp#breast_risk
- National Comprehensive Cancer Network. (2017). NCCN clinical practice guidelines in oncology: Genetic/familial high-risk assessment: Breast and ovarian. Version 1.2018. Available at https://www.nccn.org/professionals/physician_gls/f_guidelines.asp#breast_risk

Information for Patients

- National Cancer Institute. Mammograms patient information page. Available at http://www.cancer.gov/types/breast/mammograms-fact-sheet
- National Cancer Institute. Breast Cancer – Patient Version. Available at http://www.cancer.gov/types/breast

Online Provider Resources

- National Cancer Institute. Breast Cancer Risk Assessment Tool. Available at http://www.cancer.gov/bcrisktool/Default.aspx

Sexually Transmitted Disease / Infection Screening and Treatments

Note that the summary of cited guideline recommendations provided in this section reflect the ages of eligibility for the FPP, and do not include guideline recommendations for individuals outside this range.

Screening and treatment of STD/STIs must follow the current guidelines for screening and treatment from the Centers for Disease Control and Prevention (CDC). A risk assessment should be done for all individuals to determine what testing is indicated and documented in the medical record. Following is a brief overview of STD/STI screening recommendations (for more detailed information, go to the CDC screening link above):

HIV Screening:

- Contractors must provide HIV testing, either on-site or by referral. If HIV testing is done, verbal or written consent should be documented in the medical record. If testing is indicated and the person declines, this should be documented. The following should be considered when testing:
- All individuals 13 to 64 years of age should be screened at least once for HIV, using a policy that provides HIV education and allows individuals to opt out of screening if desired. With opt-out screening, individuals are informed, prior to testing, that HIV testing will be done as part of the general consent for care and they are free to decline testing if they choose to do so; if they do not decline, the test is performed.
- Individuals who engage in risky sexual practices or share injection drug paraphernalia should be tested annually.

- Individuals who seek testing or treatment of STD/STIs should be tested for HIV at the same time.
- Contractors may provide negative HIV test results to individuals in person, by telephone, or by the same method or manner as the results of other diagnostic or screening tests. The provision of negative test results by telephone must follow procedures that address a person's confidentiality, identification of the person, and prevention counseling.
- Contractors must always provide positive HIV test results to individuals in a face-to-face encounter with an immediate opportunity for counseling and referral to community support services. Test results must be provided by staff knowledgeable about HIV prevention and HIV testing.
- Individuals whose risk assessment reveals high-risk behaviors should be provided directly or referred for, more extensive risk reduction counseling by a Department of State Health Services (DSHS) HIV/STD Program trained risk reduction specialist.
- Persons with a diagnosis of HIV should be referred to a DSHS HIV/STD Program contractor for treatment and monitoring.
- To find a DSHS HIV/STD Program contractor, visit the DSHS HIV/STD website.

Chlamydia and Gonorrhea Testing:

Chlamydia and gonorrhea screening must be provided by contractors.

Annual chlamydia and gonorrhea screening should be provided for all sexually active women under 25 years of age. If a pelvic examination will not be performed, as in asymptomatic women under 21 years of age and other women who decline a pelvic examination, screening can be performed using a nucleic acid amplification technique on a urine sample or a patient self-obtained vaginal swab.

Testing should also be done in older asymptomatic women with increased risk and in all symptomatic women. Indications include, but are not limited to:

- New or multiple sex partners;
- A partner who has another partner;
- Exposure to an STD/STI;
- Symptoms or signs of cervicitis or an STD/STI;
- History of pelvic inflammatory disease;
- A positive test for an STD/STI in the prior 12 months; and
- Sex work or drug use.

Treated individuals should be retested approximately 3 to 4 months after treatment to assess evidence of reinfection.

All women who are pregnant or attempting pregnancy should be tested.

Routine screening of males for chlamydia and gonorrhea is not recommended but should be considered in settings where the prevalence of infection is high such as correctional facilities and adolescent clinics.

Herpes Simplex Virus (HSV) Screening:

The following should be considered with HSV screening:

- Routine screening of asymptomatic individuals for genital herpes simplex virus (HSV) infection is not recommended in the general or pregnant population.
- Testing, counseling, and treatment of symptomatic individuals (i.e., presence of genital lesions), as well as management of affected pregnant individuals, should follow current CDC guidelines.
- The preferred tests for confirmation of the diagnosis in individuals with active genital ulcers or mucocutaneous lesions are cell culture and polymerase chain reaction (PCR) assay.
- Type-specific serologic testing may be appropriate in some circumstances:
  - For men and women presenting for evaluation of an STD/STI (especially those who report multiple sexual partners), and persons with HIV infection;
  - For men who have sex with men and unknown HSV infection status, type-specific serologic testing may be appropriate in the evaluation of an undiagnosed genital tract infection;
  - When the diagnosis is suspected, but no lesions are present (a culture or PCR assay is not indicated if no lesions are present);
  - When the diagnosis is uncertain and virologic tests (i.e., culture and PCR) are negative in a symptomatic patient; or
  - For counseling patients regarding the risk of infection by a partner with known infection, especially during pregnancy.

Syphilis screening (men and non-pregnant women):

- Men and non-pregnant women who are at increased risk of syphilis infection should undergo screening for syphilis.

- Men who have sex with men, and men and women who are living with HIV, have the highest risk for syphilis infection.
- Other factors associated with increased prevalence of syphilis infection are a history of incarceration or commercial sex work.
- According to 2014 surveillance data, approximately 91 percent of cases of syphilis occurred in men, with the highest rates in men 20 to 29 years of age.
- Syphilis prevalence (per 100,000 population) in the U.S. varied by race and ethnicity in 2014:
  - Black: 18.9
  - Hispanic and American Indian/Alaska Native: 7.6
  - Native Hawaiian/Pacific Islander: 6.5
  - White: 3.5
  - Asian: 2.8
- Routine screening for syphilis in a non-pregnant population that is not at increased risk of syphilis infection is not recommended because it may yield a high false-positive rate, leading to overtreatment.
- Screening for other infections and more frequent screening should be considered as appropriate based on the person's condition, risk factors, and concerns.
- Pregnant women:
  - All pregnant women should undergo screening for syphilis, HIV (by an opt-out policy), and hepatitis B surface antigen as early as possible in the pregnancy.
  - Individuals under 25 years of age, and women at increased risk should also have chlamydia and gonorrhea testing.
  - Repeat testing in the third trimester is recommended for individuals at increased risk of new infection.

Patient-Delivered Partner Therapy

Patient-Delivered Partner Therapy (PDPT) is the practice of providing therapy to the sexual partner(s) of a person being treated for chlamydia or gonorrhea without first developing a patient-clinician relationship with the partner(s). Untreated partners can reinfect treated individuals and expose others to infection.

Providers are encouraged to implement PDPT by providing individuals who are being treated for either chlamydia or gonorrhea with medications or prescriptions the partner(s) can use to be treated as well.

Providers may not receive reimbursement for providing partner treatment under this policy to persons who have not been seen as patients.

References

- American College of Obstetricians and Gynecologists. Committee Opinion No. 598: The initial reproductive health visit. *Obstet Gynecol* (2014) 123: 1143-1147. Available at http://www.acog.org/Resources_And_Publications/Committee_Opinions/Committee_on_Adolescent_Health_Care/The_Initial_Reproductive_Health_Visit
- Branson, BM., et al. Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. *MMWR* (2006) 55(RR14): 1-17. Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm
- Centers for Disease Control and Prevention. Genital herpes. Available at http://www.cdc.gov/std/Herpes/default.htm
- Centers for Disease Control and Prevention. Pregnant women, infants, and children: An opt-out approach to HIV screening. Available at http://www.cdc.gov/hiv/group/l/pregnantwomen/opt-out.html
- Centers for Disease Control and Prevention. Sexually transmitted diseases: Treatment. Available at http://www.cdc.gov/std/treatment/default.htm
- Centers for Disease Control and Prevention. STD & HIV Screening Recommendations. Available at http://www.cdc.gov/std/prevention/screeningreccs.htm
- U.S. Preventive Services Task Force. Screening for syphilis infection in non-pregnant adults and adolescents: U.S. Preventive Services Task Force recommendation statement. *JAMA* (2016) 315(21): 2321-2327. Available at http://jamanetwork.com/journals/jama/fullarticle/2526645

Expedited (Patient-Delivered) Partner Therapy (information for Patients and Providers):

- Centers for Disease Control and Prevention. Expedited partner therapy website. Available at http://www.cdc.gov/std/ept/
- Texas Dept. of State Health Services. Expedited partner therapy website. Available at http://www.dshs.state.tx.us/hivstd/ept/default.shtm

Healthy Lifestyle Intervention

All individuals should receive a health risk survey at least annually, to determine

areas where lifestyle modifications might reduce the risk of future disease and improve health outcomes and quality of life.

Counseling on Healthy Lifestyle Choices

- All individuals should be advised not to smoke or to use tobacco products, and to avoid exposure to second-hand smoke as much as possible. Those who use tobacco products should be advised to quit and assessed for their readiness to do so at each encounter.
- Individuals should be counseled on healthy eating patterns and offered access to relevant information.
- Individuals should be advised to limit their salt intake.
- Individuals should be advised to engage in at least 30 minutes of physical activity or resistance training, tailored to their individual health condition and risks, at least 3 days per week, with no more than 2 consecutive inactive days. More frequent and longer duration (e.g., 60 minutes/day) activity is better.
- See the following section details on why and how to achieve some of these goals.

Diet and Nutrition

There is strong evidence that nutrition plays an important role in our risk of disease. Dietary patterns that emphasize a lower percentage of total calories from fat, reduced amounts of saturated fats, and reduced sodium intake while achieving and maintaining a healthy body weight, have been shown to reduce the risk of cardiovascular disease, the most common cause of death in both men and women in the United States. No single diet has been shown to be the best, and providers should counsel individuals on a variety of healthy eating patterns tailored to their particular health condition and cultural background, while preserving the pleasure of meals and eating.

Healthy Dietary Patterns

Two dietary patterns that have been shown to improve some measures of cardiovascular risk are the Dietary Approaches to Stop Hypertension (DASH) and Mediterranean (MED) diets. Both dietary patterns emphasize reduced saturated fat and red meat; and increased fiber, vegetables, fruits, fish, oils, and nuts, while allowing wide freedom of food choices to accommodate eating preferences and cultural differences among individuals.

The MED diet emphasizes:

- Increased servings of fruits (particularly fresh fruits), vegetables (particularly green and root vegetables), whole grains (such as whole-grain breads, rice, pasta, and cereals), and fatty fish (which are rich in omega-3 fatty acids);
- Reduced amounts of red meat (emphasizing lean meats when meat is eaten);
- Substituting lower fat or fat-free dairy products for higher fat options; and
- Using oils (such as olive or canola), nuts (such as walnuts, almonds, or hazelnuts), or margarines containing flaxseed or rapeseed oil, in place of butter and other saturated fats.

The DASH diet is:

- High in vegetables, fruits, low-fat or fat-free dairy products, whole grains, poultry, fish, legumes, and nuts; and
- Low in sweets, sugar-sweetened beverages, and red meats; and
- Lower in total fat and saturated fat than a typical American diet.

Dietary counseling on healthy eating patterns, such as those described above, provided as a routine part of an individual encounter, has been shown to reduce blood pressure in those with type 2 diabetes or risk factors for cardiovascular disease, including those with mild untreated hypertension. For individuals with normal or modestly elevated cholesterol, regardless of gender or ethnicity, following a DASH dietary pattern can reduce low-density-lipoprotein cholesterol (LDL-cholesterol) and high-density-lipoprotein cholesterol (HDL-cholesterol). Following a DASH dietary pattern can reduce blood pressure in all individuals, regardless of age, sex, and ethnicity, including those with mild untreated hypertension.

Salt Intake

There is strong evidence that reducing sodium (salt) intake reduces blood pressure in individuals with normal blood pressure as well as those with mild to moderate hypertension, regardless of sex, ethnicity, and age. This holds true even if no other dietary changes are made. Therefore, some individuals who consider the dietary patterns described above too drastic a change can reduce their blood pressure just by lowering their salt intake. Those who adopt a DASH dietary pattern and reduce their salt intake can lower their blood pressure even more. All individuals should receive advice to limit their salt intake and be counseled on ways to do so.

Cholesterol

In spite of much public attention given to cholesterol in the diet as a cause of poor health, there has been very little research on the effect of reducing dietary cholesterol on the risk of future disease; therefore, no recommendation can be made to counsel individuals on dietary cholesterol intake specifically.

Physical Activity

Regular aerobic physical activity (e.g., walking, jogging, dancing, swimming, water-walking, gardening, climbing stairs, even house cleaning) and resistance training (e.g., working with light weights or elastic bands) can reduce the risk of serious disease by lowering LDL-cholesterol and blood pressure. Individuals should be encouraged to engage in at least 30 minutes of an activity they enjoy, suitable to their current health status and risk, at least 3 times a week, with no more than two consecutive inactive days. More intensive physical activity (e.g., up to 60 minutes at a setting, more sessions per week), for those whose health status permits, offer more benefit.

Reference

- National Heart, Lung, and Blood Institute. Lifestyle interventions to reduce cardiovascular risk: Systematic Evidence Review from the Lifestyle Work Group (2013). Available at http://www.nhlbi.nih.gov/health-pro/guidelines/in-develop/cardiovascular-risk-reduction/lifestyle

Information for Patients and Educators

- American Heart Association. Healthy Eating. Provides information on food choices, recipes, how to eat healthy when dining out, and how to shop for groceries with a focus on healthy eating. Available at http://www.heart.org/HEARTORG/HealthyLiving/HealthyEating/Healthy-Eating_UCM_001188_SubHomePage.jsp
- American Heart Association. Get moving! Easy tips to get active. Provides information on physical activity and fitness. Available at http://www.heart.org/HEARTORG/HealthyLiving/PhysicalActivity/Physical-Activity_UCM_001080_SubHomePage.jsp
- American Heart Association. Sodium and Salt. Provides information on ways to reduce dietary salt intake. Available at http://www.heart.org/HEARTORG/HealthyLiving/HealthyEating/Nutrition/Sodium-and-Salt_UCM_303290_Article.jsp#.WThZ4-v1DRY

- Mayo Clinic. Healthy diets. Available at http://www.mayoclinic.org/healthy-lifestyle/nutrition-and-healthy-eating/basics/healthy-diets/hlv-20049477
- Mayo Clinic. DASH diet: Healthy eating to lower your blood pressure. Available at http://www.mayoclinic.org/healthy-lifestyle/nutrition-and-healthy-eating/in-depth/dash-diet/art-20048456
- Mayo Clinic. DASH diet recipes. Available at http://www.mayoclinic.org/healthy-lifestyle/recipes/dash-diet-recipes/rcs-20077146
- Mayo Clinic. Mediterranean diet recipes. Available at http://www.mayoclinic.org/healthy-lifestyle/nutrition-and-healthy-eating/in-depth/mediterranean-diet-recipes/art-20046682

Diabetes Mellitus Screening

Who Should Be Screened for Diabetes

The criteria below apply to non-pregnant patients only.

- Begin screening all adults at 45 years of age.
- Screen adults < 45 years of age who are overweight or obese (BMI $\geq$ 25 kg/m^2 [BMI $\geq$ 23 kg/m^2 for Asian Americans]) with 1 or more risk factor. An adult BMI calculator is available from the Centers for Disease Control and Prevention (CDC).
- Screen overweight or obese children or adolescents (19 years of age or younger) with 2 or more additional risk factors. To determine whether the individual is overweight or obese, see the CDC web page Defining Childhood Obesity and the child and teen BMI calculator provided by the CDC.
- If screening test results are normal, retest at least every 3 years. Consider more frequent testing in patients with risk factors.
- Patients with prediabetes (IFG or IGT) should be retested every year.
  - IFG and IGT refer to laboratory values that are above the normal range but do not meet the diagnostic criteria for diabetes. Persons with these results are said to have "prediabetes."
- All women with a diagnosis of gestational diabetes in a recent pregnancy should have diabetes screening with a 2-hour oral glucose tolerance test at 6-12 weeks postpartum, regardless of other risk factors.
- All women with any history of gestational diabetes should have testing for diabetes and prediabetes at least every 3 years, regardless of other risk factors.

Risk Factors for Diabetes

- High-risk race or ethnicity (e.g., Latino, African American, Asian American, Native American, Pacific Islander);
- Diabetes in a first-degree relative;
- Physical inactivity;
- Women who ever had gestational diabetes or delivered a baby weighing > 9 pounds;
- History of prediabetes: hemoglobin A1C > 5.7 percent (39 mmol/mol), impaired fasting glucose (IFG), or impaired glucose tolerance (IGT) in previous testing;
- HDL cholesterol < 35 mg/dL (0.90 mmol/L) and/or serum triglyceride level > 250 mg/dL (2.82 mmol/L);
- A history of polycystic ovary syndrome;
- A diagnosis of hypertension;
- A history of cardiovascular disease; or
- Any other condition in which insulin resistance is common, such as severe obesity or acanthosis nigricans.

Diagnostic Criteria

Any one or more of the following results, confirmed on repeat testing, meets the criteria for a diagnosis of diabetes (repeat testing for confirmation is not required in the presence of unequivocal clinical hyperglycemia):

- Fasting plasma glucose (after no caloric intake for a minimum of 8 hours) > 126 mg/dL (7.0 mmol/L);
- Oral glucose tolerance test (OGTT) with a 2-hour postprandial glucose level > 200 mg/dL (11.1. mmol/L) following a 75-g glucose load;
- Hemoglobin A1C > 6.5 percent (48 mmol/mol) (For diagnosis of type I diabetes in individuals with acute hyperglycemic symptoms, blood glucose testing is preferred.); or
- Random plasma glucose > 200 mg/dL (11.1. mmol/L) in the setting of a hyperglycemic crisis or classic symptoms of hyperglycemia. (Confirmation by repeat testing is not required in this setting.)

Test	Criteria to Diagnose Diabetes Mellitus	Comments

Fasting plasma glucose	>/= 126 mg/dL (7.0 mmol/L)	After no caloric intake for a minimum of 8 hours
Oral glucose tolerance test (with a 75-g glucose load)	2-hour glucose >/= 200 mg/dL (11.1. mmol/L)	
Hemoglobin A1C	>/= 6.5% (48 mmol/mol)	For diagnosis of type I diabetes in individuals with acute hyperglycemic symptoms, blood glucose testing is preferred
Random plasma glucose	>/= 200 mg/dL (11.1. mmol/L)	If this occurs in the setting of a hyperglycemic crisis or classic symptoms of hyperglycemia, confirmation by repeat testing is not required

Table: Diagnostic Criteria for Diabetes Mellitus. All initial results should be confirmed with repeat testing.

References

- American College of Obstetricians and Gynecologists (2013). Practice Bulletin No. 137: Gestational diabetes mellitus. *Obstet Gynecol*. 122 406-416.
- American Diabetes Association. Standards of medical care in diabetes – 2018. *Diabetes Care* (2018); 41(Suppl. 1). Available at http://care.diabetesjournals.org/content/41/Supplement_1

Resources for Patients and Educators

- American Diabetes Association home page: http://www.diabetes.org
- American Diabetes Association DiabetesPro website (information for providers of care) http://professional.diabetes.org

- American Diabetes Association Diabetes Educators (information and resources for both patients and educators) http://professional.diabetes.org/diabetes-education
- Centers for Disease Control and Prevention. Adult BMI calculator. Available at http://www.cdc.gov/healthyweight/assessing/bmi/adult_bmi/english_bmi_calculator/bmi_calculator.html
- Centers for Disease Control and Prevention. BMI calculator for child and teen. Available at http://nccd.cdc.gov/dnpabmi/Calculator.aspx
- Centers for Disease Control and Prevention. Defining childhood obesity web page (provides definition of overweight and obesity in children and adolescents 2 to 19 years of age, and link to BMI calculator for children and teens). Available at http://www.cdc.gov/obesity/childhood/defining.html
- National Diabetes Education Initiative (patient education handouts and links to professional resources): http://www.ndei.org
- National Institute of Diabetes and Digestive Diseases. National Diabetes Education Program (resources for patients and educators). Available at http://www.niddk.nih.gov/health-information/health-communication-programs/ndep/pages/index.aspx
- National Heart, Lung, and Blood Institute Aim for a Healthy Weight website: https://www.nhlbi.nih.gov/health/educational/lose_wt

Hypertension Screening

All individuals, including those with hypertension, should be advised to adhere to a healthy lifestyle as described in the Healthy Lifestyle Intervention section of this clinical policy manual.

Classification of BP and diagnosis of hypertension:

In the United States, high blood pressure (BP) is the second leading cause of preventable death after cigarette smoking and is the most important modifiable risk factor for death due to cardiovascular disease. Because hypertension is generally asymptomatic, it is important that all persons be screened at least annually for elevated BP.

The following table provides guidance on diagnosis of hypertension in adults. Recent guidelines emphasize greater reliance on home BP monitoring to aid in the diagnosis of hypertension when clinic readings are high normal, borderline high, or

elevated. It is generally agreed that clinic BP measurements are often higher than home BP measurements, particularly in the higher ranges of BP.

BP (mm Hg)	Category
< 120/80	Normal
120-129/<80	Elevated
130-139/80-89	Stage 1 hypertension
>/= 140/90	Stage 2 hypertension

Measurement of blood pressure:

- For diagnosis of hypertension, BP readings should be based on the average of accurate measurements taken on 2 or more occasions using proper technique.
- Ambulatory or home BP monitoring should be performed to confirm the diagnosis of hypertension.
- Adults not being treated for hypertension who have office BP readings of 130/80 to 160/100 mm Hg should be screened for white coat hypertension (WCH, high BP in the clinic but normal BP outside the clinic) using ambulatory or home BP monitoring.
- Periodically monitor adults with WCH using ambulatory or home BP monitoring to assess for development of sustained hypertension.
- Adults not being treated for hypertension who have office BP readings of 120/75 to 129/79 mm Hg consistently should be screened for masked hypertension (normal BP in the clinic but high BP outside the clinic) using ambulatory or home BP monitoring.

Instructions for home BP monitoring:

- Patients should receive instruction for home BP monitoring, including interpretation of results, under medical supervision.
- An automated validated device should be used, preferably with the ability to store readings in memory.
- Correct cuff size should be verified, and the patient should be instructed to measure BP in the arm with the higher reading if a significant difference is observed between arms.
- Instruct the patient to rest quietly for at least 5 minutes, and avoid exercise, caffeine, and smoking for at least 30 minutes before taking BP.

- Instruct the patient to sit upright in a straight-backed chair with feet flat on the floor, legs uncrossed, and the arm supported on a flat surface with the upper arm at heart level.
- The bottom of the cuff should sit directly above the antecubital fossa.
- Two readings, taken 1 minute apart, should be done twice daily, in the morning before taking any medications, and in the evening before eating supper. Measurements should be done daily, for one week before a clinic visit.
- Monitors with stored memory should be brought to any clinic appointments.
- Clinical decision making should be based on the average of readings taken on 2 or more occasions.

Nonpharmacologic intervention:

All patients, regardless of BP category should receive instruction in healthy lifestyle habits, with regular reinforcement of teaching.

- Weight loss should be advised for adults who are overweight or obese.
- Persons with elevated BP or hypertension should adopt a heart-healthy diet (e.g., DASH diet) to reduce BP.
- Sodium intake should be reduced.
- Potassium intake should be increased, preferably by dietary modification.
- Physical activity should be increased using a structured exercise program.
- Alcohol intake should be avoided or moderated (</= 1 standard drink daily for women, </= 2 standard drinks daily for men).

References

- Carey, R. M., Whelton, P. K. (2018). Prevention, detection, evaluation, and management of high blood pressure in adults: Synopsis of the 2017 American College of Cardiology/American Heart Association hypertension guideline. *Ann Intern Med, 168*(5), 351-358. Available at http://annals.org/aim/fullarticle/2670318/prevention-detection-evaluation-management-high-blood-pressure-adults-synopsis-2017
- Whelton, P. K., Carey, R. M., Aronow, W. S., Casey, D. E., Collins, K. J., Himmelfarb, C. D., Wright, J. T. (2017). ACC/AHA/AAPA/ABC/ACPM/AGS/APha/ASH/ASPC/NMA/PCNA Guideline for the prevention, detection, evaluation, and management of high blood pressure in adults. *Hypertension, 71*(6), e13-e115. Available at http://hyper.ahajournals.org/content/71/6/e13.long

- Whelton, P. K., Carey, R. M., Aronow, W. S., Casey, D. E., Collins, K. J., Himmelfarb, C. D., Wright, J. T. (2017). 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APha/ASH/ASPC/NMA/PCNA Guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: Executive Summary: A report of the American College of Cardiology/American Heart Association task force on clinical practice guidelines. *J Am Coll Cardiol, 71*(19), 2199-2269. Available at https://www.sciencedirect.com/science/article/pii/S073510971741518X?via%3Dihub

Resources for Patients and Educators

- American Heart Association. High blood pressure. Provides information on the meaning and importance of high blood pressure, risks for and prevention of high blood pressure, blood pressure monitoring, and treatment of high blood pressure. Available at http://www.heart.org/HEARTORG/Conditions/HighBloodPressure/High-Blood-Pressure_UCM_002020_SubHomePage.jsp
- National Heart, Lung, and Blood Institute. Description of high blood pressure. Provides a plain-language discussion of the prevention, diagnosis, and treatment high blood pressure. Available at http://www.nhlbi.nih.gov/health/health-topics/topics/hbp

Resources for Providers

- American Society of Hypertension. Hypertension Guidelines website: http://www.ash-us.org/About-Hypertension/Hypertension-Guidelines.aspx

Screening for High Cholesterol

Note that the summary of cited guideline recommendations provided in this section reflect the ages of eligibility for the FPP, and do not include guideline recommendations for individuals outside this eligibility range.

The diagnosis and treatment of elevated blood cholesterol is a complex subject and a complete discussion is beyond the scope of this clinical policy manual. For more information, providers are referred to the reference section below and relevant textbooks.

Rationale for Cholesterol Screening

Evidence shows that a healthy lifestyle (following a heart healthy diet, maintaining a healthy weight, regular exercise, and avoidance of tobacco products) reduces the risk of cardiovascular disease. In certain persons with specific risk factors, cholesterol-lowering medications (i.e., statins) can further reduce the risk of an adverse health event. Measurement of blood cholesterol is a component of the individual risk assessment in some patients.

Who Should Be Screened for High Cholesterol

- All men 35 years of age and older;
- Men 20-35 years of age with increased risk for coronary heart disease;
- Women 20 years of age and older with increased risk for coronary heart disease (CHD);
- No recommendation is made regarding routine screening in men 20-35 years of age, or in women 20 years of age or older without increased risk of CHD.

Risk Factors

Increased risk of CHD is defined by the presence of any 1 of the risk factors below. Greater risk results from the presence of multiple risk factors.

- Diabetes;
- Personal history of previous CHD or non-coronary atherosclerosis;
- Family history of cardiovascular disease in men before age 50 and in women before age 60;
- Tobacco Use;
- Hypertension; or
- Obesity (body mass index ≥ 30 kg/m^2).

Screening Frequency

The optimal interval for screening is uncertain. Reasonable options include every 5 years, shorter intervals for people who have lipid levels close to those warranting therapy, and longer intervals for those not at increased risk who have had repeatedly normal lipid levels. An age at which to stop screening has not been established.

Screening Method

The preferred screening test for elevated cholesterol is the serum lipid panel (total cholesterol, high-density lipoprotein [HDL] cholesterol, and low-density lipoprotein [LDL] cholesterol) in the fasting or non-fasting state. If non-fasting results are used, only the total cholesterol and HDL-cholesterol are reliable. Abnormal screening results should be confirmed by a repeat sample on a separate occasion, and the average of both results should be used for risk assessment.

Evaluation of Screening Results

Results of the lipid profile should be interpreted in the context of the individual's risk factors and 10-year estimated risk of atherosclerotic cardiovascular disease (ASCVD; defined as acute coronary syndrome, myocardial infarction, stable or unstable angina, stroke, transient ischemic attack, coronary or other arterial revascularization procedure, or atherosclerotic peripheral arterial disease). A risk calculator for 10-year ASCVD risk is available from the American College of Cardiology and American Heart Association.

Studies have shown a benefit of statin therapy in individuals with the following risk profiles:

- All individuals with clinical ASCVD, regardless of lipid profile results;
- Any individuals with LDL-cholesterol $\geq$ 190 mg/dL;
- Individuals 40 years of age or older with diabetes and LDL-cholesterol $\geq$ 70-189 mg/dL and no clinical ASCVD;
- Individuals 40 years of age or older with diabetes and LDL-cholesterol 70-189 mg/dL and no clinical ASCVD; or
- Individuals of any age without diabetes or clinical ASCVD, with LDL-cholesterol 70-189 mg/dL and 10-year ASCVD risk $\geq$ 7.5 percent .

References

- Stone NJ, et al. 2013 ACC/AHA Guidelines on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults. *Circulation* (2014). 129(25 Suppl 2): S1-S45. Available at https://circ.ahajournals.org/content/early/2013/11/11/01.cir.0000437738.63853.7a.full
- National Heart, Lung, and Blood Institute. Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Cholesterol in Adults (Adult Treatment Panel III). NIH

Publication No. 01-3670, May 2001. Available at http://www.nhlbi.nih.gov/files/docs/guidelines/atp3xsum.pdf
- U.S. Preventive Services Task Force. The Guide to Clinical Preventive Services, "Lipid Disorders in Adults" (2014). Page 45. Available at http://www.ahrq.gov/sites/default/files/publications/files/cpsguide.pdf

Further Reading

- Pursnani A, et al. Guideline-based statin eligibility, coronary artery calcification, and
- cardiovascular events. JAMA (2015) 314:134-141. Available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4754085/

Resources for Providers

- ASCVD Risk Estimator from the American College of Cardiology. Provides an estimate of the 10-year risk of developing ASCVD. Available at http://tools.acc.org/ASCVD-Risk-Estimator/

Postpartum Depression Screening

Prevalence and Risk Factors for Postpartum Depression

As many as 80 percent of new mothers experience a brief episode of the "baby blues" which may last up to about 2 weeks. Approximately 5-25 percent of new mothers will experience postpartum depression that warrants intervention. It typically begins in the first 4 to 6 weeks after birth of the infant but may develop any time in the first year.

Risk factors for postpartum depression include all of the following:

- Lack of social support;
- Symptoms of depression (especially in the third trimester) or anxiety during the pregnancy;
- Prior psychiatric illness or poor mental health, especially prior postpartum depression;
- Family history of depression, anxiety, or bipolar disorder;
- Low socio-economic status or low educational level;
- Poor income or unemployment;
- Poor relationship with the partner or father of the baby;
- A negative attitude toward the pregnancy;
- A recent stressful life event or perceived stress;

- Intention to return to work;
- A history of bothersome premenstrual syndrome;
- A history of physical, sexual, or psychological abuse; domestic violence;
- Stress related to child care issues;
- Medical illness or prematurity in the infant;
- A temperamentally difficult infant; or
- Immigrant from another country.

Common signs and symptoms of postpartum depression include the following (note that some or none of these symptoms may be apparent):

- Difficulty sleeping even when the baby is sleeping;
- Tearfulness, prone to crying;
- Excessive worrying about the baby;
- Excessive anxiety;
- Feelings of guilt, such as the feeling that she is not a good mother;
- Flat affect; or
- Poor appetite.

Screening for Postpartum Depression

Providers are encouraged to review The Texas Clinician's Postpartum Depression Toolkit for a more detailed review of screening for postpartum depression.

Because postpartum depression can be a serious, and sometimes life-threatening condition, all new mothers should have screening for postpartum depression at the postpartum visit. For those who screen negative, repeat screening should be considered at a later visit or when the mother takes her baby in for a checkup.

A standardized self-administered screening tool with review and follow-up questions in a face-to-face interview with the provider will ensure consistency and efficiency in the screening process. The following postpartum depression screening tools are available on-line, and have been validated for use in postpartum patients:

- Edinburgh Postnatal Depression Scale (EPDS; Cox, Holden, & Sagovsky, 1987)
- Patient Health Questionnaire-9 (PHQ-9; Spitzer, Kroenke, & Williams, 1999)
- Postpartum Depression Screening Scale (PDSS; Beck & Gable, 2001)
  To ensure that all patients are screened without undue interruption of clinic workflow, a convenient approach to screening is the following:

- Give each postpartum woman a screening tool to complete while she waits for her visit with the provider.
- Score the tool and assess whether the screen is positive or negative:
  - EPDS: A score of 10 or more suggests depressive symptoms, a score of 13 or more indicates a high likelihood of major depression; a score of 1 or more on question #10 is an automatic positive screen because it indicates possible suicidal ideation and should be addressed appropriately.
  - PHQ-9: A score of 10 or more indicates a high risk of having or developing depression; a score of 2 or more on question #9 is an automatic positive screen because it indicates possible suicidal ideation and should be addressed appropriately.
  - PDSS Full form: A score of 60 or more suggests depressive symptoms, a score of 81 or more indicates a high likelihood of major depression; a score of 6 or more on the SUI (suicidal thoughts) subscale is an automatic positive screen because it indicates possible suicidal ideation and should be addressed appropriately.
  - PDSS Short form: A score of 14 or more indicates a high risk of major depression; a score of 2 or more on question #7 is an automatic positive screen because it indicates possible suicidal ideation and should be addressed appropriately.
- The provider should review the screen and discuss it with the woman and ask follow-up questions to evaluate her risk of postpartum depression.

Screening for Suicide Risk

Any individual with a positive screen based on responses to questions related to suicide risk, and any individual who expresses suicidal thoughts or ideation must be evaluated immediately for suicide risk. If the individual is felt to be acutely at risk of suicide, she must be referred for emergent evaluation and/or hospitalization as indicated.

Referral for Treatment

Individuals in need of treatment for postpartum depression should be referred to a provider of behavioral health services. Providers must have arrangements in place for appropriate referral of individuals to behavioral health providers in their area. For information on local behavioral health care providers, refer to the website of the Office of Mental Health Coordination, Texas Health and Human Services, or call 211.

Coding for postpartum depression services

The following Current Procedural Terminology (CPT) codes are covered under the Family Planning Program:

99201	99202	99203	99204	99205
99211	99212	99213	99214	99215
90791	90792			

References

- American College of Obstetricians and Gynecologists Committee Opinion no. 630. Screening for perinatal depression. *Obstet Gynecol* (2015). 125: 1268-1271. Available at http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Screening-for-Perinatal-Depression
- Hirst KP and Moutier CY. Postpartum major depression. *American Family Physician* (2010). 82: 926-933. Available at http://www.aafp.org/afp/2010/1015/p926.html
- Norhayati MN, et al. Magnitude and risk factors for postpartum symptoms: A literature review. *J Affect Disord* (2015). 175: 34-52.
- O'Connor E, et al. Primary care screening for and treatment of depression in pregnant and postpartum women: Evidence report and systematic review for the US Preventive Services Task Force. *JAMA* (2016). 315: 388-406.

Resources for Patients and Providers

- American Academy of Family Physicians. Postpartum Depression web page. Information for patients and providers on postpartum depression. Available at http://familydoctor.org/familydoctor/en/diseases-conditions/postpartum-depression.html
- American Academy of Family Physicians. Postpartum Depression Action Plan. Available at http://familydoctor.org/familydoctor/en/diseases-conditions/postpartum-depression/treatment/postpartum-depression-action-plan.html
- Office of Mental Health Coordination website, Texas Health and Human Services, provides links to information for providers and patients in Texas on

a variety of behavioral health topics, and a link to the Substance Abuse and Mental Health Services Administration (SAMHSA) behavioral health treatment services locator. Available at http://mentalhealthtx.org/

- STEP-PPD Support and training to enhance primary care for postpartum depression website. Provides links to resources, including postpartum depression screening tools, online training, case studies, classroom materials, "Clinician's Pocket Guide," and other materials. Available at https://step-ppd.com/
- Texas Health and Human Services. The Texas Clinician's Postpartum Depression Toolkit. Contains a review of the diagnosis and treatment of postpartum depression for the primary care provider, including a section on covered services, coding, and billing for services provided under Texas state healthcare programs. Available at https://www.healthytexaswomen.org/provider-resources#family-planning-program

Perinatal Clinical Policy

Prenatal services should be provided based on ACOG guidelines.

Components of Initial & Return Visit Prenatal Interventions/Screening

Prenatal Visit – The initial encounter with a pregnant woman includes:

Complete history, physical examination, assessment, planning, treatment, counseling and education, referral as indicated, routine prenatal laboratory tests and additional laboratory tests as indicated by history, physical exam and/or assessment.

Return Prenatal Visit - Follow up prenatal visit includes interval history, physical examination, risk assessment, medical services, nutritional counseling, psychosocial counseling, family planning counseling, and client education regarding maternal and child health topics. Hemoglobin and/or hematocrit, and urinalysis for protein and glucose are also included.

Perinatal Histories

Prenatal Visit

The comprehensive medical history documented at the initial prenatal visit must at least address the following:

- current health status, including acute and chronic medical conditions, if any;
- significant past illnesses, including hospitalizations;
- previous surgeries and biopsies;
- blood transfusions and other exposure to blood products;
- mental health history (e.g., depression, anxiety);
- current medications, including prescription, over the counter (OTC) as well as complementary and alternative medicines (CAM);
- allergies, sensitivities or reactions to medicines and other substances (e.g. latex, seafood);
- immunization status/assessment, including rubella status;
- reproductive health history, including
- pertinent sexual behavior history, including family planning practices (i.e., past contraceptive use), number of partners, gender of sexual partners;
- sexually Transmitted Infections (STIs) (including hepatitis B and C), and HIV history, risks, and exposure;
- pertinent partner history, including injectable drug use, number of partners;
- menstrual history, including last normal menstrual period;
- obstetrical history, detailed;
- gynecological and urological conditions;
- cervical cancer screening history (date and results of last Pap test or other cervical cancer screening test, note any abnormal results and treatment); and
- social history/health risk assessment (HRA), including:
  - home environment, to include living arrangements;
  - family dynamics with assessment for family violence (including safety assessment, when indicated) (Mandated by Texas Family Code, Chapter 261 and Rider 19);
  - tobacco/alcohol/recreational drug use/abuse and/or exposure;
  - drug dependency (including type, duration, frequency, route);
  - nutritional history;
  - occupational hazards or environmental toxin exposure;
  - ability to perform activities of daily living (ADLs);
  - risk assessment including, but not limited to:
  - diabetes;
  - heart disease;
  - intimate partner violence;
  - other physical or sexual abuse;

  - human trafficking;
  - injury;
  - malignancy;
  - injury;
  - malignancy;
  - family history, including genetic conditions;
- review of systems with pertinent positives and negatives documented in health record.

Return Prenatal Visits

Interval history includes:

- symptoms of infections;
- symptoms of preterm labor;
- headaches or visual changes;
- fetal movement (>18 weeks); and
- family violence screening (repeat >28 weeks).

Physical Assessments

All initial and routine prenatal visits must include an appropriate physical exam according to the purpose of visit and week of gestation. For any portion of the examination that is deferred, the reason(s) for deferral must be documented in the client health record.

Initial Prenatal Visit

- height measurement;
- weight measurement, with documentation of pre-pregnancy weight and assessment for underweight, overweight, and obesity;
- body mass index (BMI);
- blood pressure evaluation;
- cardiovascular assessment;
- clinical breast exam;
- visual inspection of external genitalia and perianal area;
- pelvic exam, including estimate of uterine size (by bimanual exam for gestational age less than or equal to 14 weeks or by fundal height for gestational age equal to or more than 14 weeks);
- fetal heart rate for gestational age > 12 weeks; and

- other systems as indicated by history and health risk assessment. (e.g., evaluation of thyroid, lungs, abdomen).

Return Prenatal Visits

- weight measurement;
- blood pressure evaluation;
- uterine size/fundal height;
- fetal heart rate (> 12 weeks);
- fetal lie/position (> 30 weeks); and
- other systems as indicated by history or other findings.

Laboratory and Diagnostic Tests

All initial and return prenatal visits must include appropriate laboratory and diagnostic tests as indicated by weeks of gestation and clinical assessment. Contractors must have written plans to address laboratory and other diagnostic test orders, results and follow-up to include:

- tracking and documentation of tests ordered and performed for each patient;
- tracking of test results and documentation in patient records; and
- mechanism to address abnormal results, facilitate continuity of care and assure confidentiality, adhering to HIPAA regulations (i.e., making results and interventions accessible to the delivering hospital, facility or provider).

Initial Prenatal Visit Laboratory and Diagnostic Tests

- blood type, Rh and antibody screen;
- sexually transmitted infection testing as indicated by risk assessment, history, and physical exam, and the following:
  - chlamydia and gonorrhea testing should be done on all patients age 25 or younger, and older individuals at increased risk of infection, even if symptoms are not present;
  - Hepatitis B Antigen (HbsAg) (Mandated by Health and Safety Code 81.090);
  - HIV, unless declined by the person, who must then be referred to anonymous testing (Mandated by Health and Safety Code 81.090);
    - Review CDC's revised recommendations for HIV testing for adults and pregnant women.
  - syphilis serology (Mandated by Health and Safety Code 81.090);
- hemoglobin and/or hematocrit;

- rubella serology, or positive immune status /immunization documented in chart;
- cervical cancer screening test (e.g., Pap test) for women 21 years and older, if indicated;
- hemoglobinopathy screening, as indicated;
- urine culture;
- TB skin test as indicated by risk assessment, history, or physical exam (see the Heartland National TB Center algorithm for pregnant individuals http://www.heartlandntbc.org/assets/products/evaluation_of_pregnant_patient_at_risk_for_tb.pdf .);
- ultrasound, as clinically indicated; and
- other laboratory and diagnostic tests as indicated by risk assessment, history and physical exam.

ACOG / ACS / ASCCP / ASCP Cervical Cancer Screening Guidelines

- Cervical cancer screening begins at age 21 years;
- Cervical cytology (Pap smear) alone, with reflex human papillomavirus (HPV) testing when cytology reveals atypical squamous cells of undetermined significance (ASCUS), every three (3) years for women between the ages of 21 and 29 years;
- Women 30 years of age and older should have co-testing with cervical cytology and HPV testing every 5 years (prefer-ed), or cervical cytology testing alone (with reflex HPV testing for ASCUS) every 3 years.
- Both liquid-based and conventional methods of cervical cytology are acceptable for screening.

Women with special circumstances, who are considered high-risk (e.g. HIV+, immunosuppressed or were exposed to Diethylstilbestrol (DES) in utero) may be screened more frequently as determined by the clinician.

Individuals already following a plan of care/algorithm may continue with that plan of care/algorithm until completed and they return to routine screening. Once the person returns to routine screening follow the guidelines above.

Return Prenatal Visits Laboratory and Diagnostic Tests

- Fetal aneuploidy screening appropriate for the gestational age at the time of testing should be offered to all patients with appropriate counseling;
- diabetes screen (24 – 28 weeks);
- Glucose Tolerance test (GTT) for abnormal diabetic screen;

- antibody screen for Rh negative individuals, not previously known to be sensitized, between 24 – 28 weeks (if negative, repeat Anti-D immune globulin at ~28 weeks; if positive, refer to specialist in high-risk obstetrics for evaluation of possible maternal Rh-D alloimmunization);
- hemoglobin and/or hematocrit (recommended recheck between 32 – 36 weeks);
- group B streptococcus screen, between 35 – 37 weeks if using screened-based approach [see the Centers for Disease Control and Prevention (CDC) revised 2002 recommendations to prevent perinatal transmission of Group B Streptococcus (GBS) infection to the neonate on the CDC web site at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5111a1.htm];
- ultrasound, as clinically indicated;
- non-stress test (NST) to assess fetal well-being, as clinically indicated;
- biophysical profile (BPP)/fetal biophysical profile (FBPP) to assess fetal wellbeing, as clinically indicated; and
- other laboratory and diagnostic as indicated by risk assessment, history and physical exam.

Diagnostic Tests and Interventions

Ultrasounds

Obstetrical ultrasounds will be reimbursed when clinically indicated, including the following:

- estimation of gestational age for women with uncertain clinical dates;
- verification of dates for women who had a previous cesarean delivery;
- vaginal bleeding of undetermined origin;
- suspected multiple gestation;
- significant uterine size/clinical dates discrepancy;
- pelvic mass;
- suspected ectopic pregnancy;
- suspected fetal death;
- suspected uterine abnormality;
- intrauterine contraceptive device localization;
- abnormal alpha-fetoprotein value;
- follow-up observation of identified fetal anomaly;
- follow-up evaluation of placental location for suspected placenta previa;
- history of previous congenital anomaly;
- serial evaluation of fetal growth in multifetal gestation;

- evaluation of fetal condition in late registrants for prenatal care; and
- other conditions associated with possible adverse fetal outcome.

Complete ultrasound – A complete evaluation of the pregnant uterus, to include fetal number, viability, presentation, dating measurements, complete anatomical survey; placental localization characterizations, and amniotic fluid assessment.

Complete ultrasound for confirmed multiple gestation – A complete evaluation of the pregnant uterus that includes viability, presentation, dating measurements, complete anatomical survey, placental localization characterizations, and amniotic fluid assessment.

Follow-up or limited ultrasound – A brief, more limited evaluation of the pregnant uterus that may follow a previous complete exam, be it an initial exam prior to 12 weeks, or be it an initial exam 12 week which is limited in scope. It includes fetal number, viability, presentation, dating measurements, limited anatomic assessment; placental localization and characterization; and amniotic fluid assessment.

Repeat D-antibody test - For all unsensitized D-negative women at 24-28 weeks of gestation followed by the administration of a full dose of D immunoglobulin if they are antibody negative. If the father is known with certainty to be Rh D-negative, this may be deferred.

Special Procedures

Non-Stress Test (NST) fetal well-being assessment to be performed in the presence of identified risk factors, as indicated, once a viable gestational age has been reached. It may be billed as often as the provider deems the procedure to be medically necessary.

Biophysical Profile (BPP)/Fetal Biophysical Profile (FBPP) – fetal well-being assessment to be performed in the presence of identified risk factors, as indicated, once a viable gestational age has been reached. It may be billed as often as the provider deems the procedure to be medically necessary.

Education and Counseling Services

Contractors must have written plans for individual education that ensure consistency and accuracy of information provided, and that identify mechanisms used to ensure client understanding of the information.

Education and counseling must be:

- documented in the client health record;
- appropriate to the person's age, level of knowledge and socio-cultural background;
- presented in an unbiased manner.

Education and counseling during the initial prenatal visit, based on health history, risk assessment and physical exam, must cover the following:

- nutrition and weight gain counseling;
- family and intimate partner violence/abuse;
- human trafficking;
- physical activity and exercise;
- sexual activity;
- environmental or work hazards;
- travel;
- tobacco cessation;
- alcohol use;
- substance abuse;
- breastfeeding;
- when and where to obtain emergency care;
- risk factors identified during visit;
- anticipated course of prenatal care;
- HIV and other prenatal tests;
- injury prevention, including seat belt use;
- cocooning infants/children against pertussis (immunization of family members and potential caregivers of infant);
- toxoplasmosis precautions;
- referral to WIC;
- use of medications (including prescription, over the counter (OTC), and complementary/alternative medicines (CAM);
- information on parenting and postpartum counseling (Mandated by Chapter 161, Health and Safety Code, Subchapter T); and
- other education and counseling as indicated by risk assessment, history and physical exam.

Education and counseling during the return prenatal visits, should be appropriate to weeks' gestation and be based on health history, risk assessment and physical exam, including, but not limited to:

- signs and symptoms of preterm labor beginning in 2nd trimester;

- signs and symptoms of labor as the patient nears term gestation;
- warning signs and symptoms of pregnancy induced hypertension (PIH);
- selecting provider for infant;
- postpartum family planning.

Tobacco Assessment and Quit Line Referral - All women receiving prenatal services should be assessed for tobacco use. Women who use tobacco should be referred to tobacco quit lines. The Texas American Cancer Society Quit Line is 1-877-YES-QUIT or 1-866-228-4327 (Hearing Impaired). The assessment and referral should be performed by agency staff and documented in the clinical record.

Information for Parents of Newborns Requirement: Chapter 161, Health and Safety Code, Subchapter T requires hospitals, birthing centers, physicians, nurse-midwives, and midwives who provide prenatal care to pregnant women during gestation or at delivery to provide the woman and the father of the infant or other adult caregiver for the infant with a resource pamphlet that includes information on postpartum depression, shaken baby syndrome, immunizations, newborn screening, pertussis and sudden infant death syndrome. In addition, it must be documented in the person's chart that she received this information and the documentation must be retained for a minimum of five years. It is recommended that the information be given twice, once at the first prenatal visit and again after delivery.

Information for Parents of Children: Chapter 161, Health and Safety Code, Subchapter T also requires hospitals, birthing centers, physicians, nurse-midwives, and midwives who provide prenatal care during gestation or at delivery to pregnant women on Medicaid to provide the woman and the father of the infant or other adult caregiver for the infant with a resource guide that includes information relating to the development, health, and safety of a child from birth until age five. The resource guide must provide information about medical home, dental care, effective parenting, child safety, importance of reading to a child, expected developmental milestones, health care and other resources available in the state, and selecting appropriate child care.

Provision of Information about Umbilical Cord Blood Donation Requirement: Chapter 162, Health and Safety Code, Subtitle H requires that a physician or other person permitted by law to attend a pregnant woman during gestation or at delivery of an infant shall provide the woman with an informational brochure, before the third trimester of the woman's pregnancy or as soon as reasonably feasible, that includes information about the uses, risks and benefits of

cord blood stem cells for a potential recipient, options for future use or storage of cord blood, the medical process used to collect cord blood, any costs that may be incurred by a pregnant woman who chooses to donate or store cord blood after delivery, and average cost of public and private storage**.** The brochure is available on the DSHS website or can be ordered from the DSHS literature warehouse. https://www.dshs.state.tx.us/pdf/umbilical_brochure_(2).pdf

Education and counseling during postpartum visits should include but not be limited to:

- Physiologic changes;
- Signs and symptoms of common complications;
- Care of the breast;
- Care of perineum and abdominal incision, if indicated;
- Physical activity and exercise;
- Breastfeeding/Infant feeding;
- Resumption of sexual activity;
- Family planning/contraception;
- Preconception counseling; or
- Depression/postpartum depression

Referral and Follow-up

Agencies must have written policies and procedures for follow-up on referrals that are made as a result of abnormal physical examination or laboratory test findings. These policies must be sensitive to patients' concerns for confidentiality and privacy and must be in compliance with state or federal requirements for transfer of health information.

For services determined to be necessary, but which are beyond the scope of the agency, patients must be referred to other providers for care. (Whenever possible, patients should be given a choice of providers from which to select.) When a patient is referred to another provider or for emergency clinical care, the agency must:

- Arrange for the provision of pertinent individual information to the referral provider (obtaining required patient consent with appropriate safeguards to ensure confidentiality – i.e., adhering to HIPAA regulations);
- Advise individual about his/her responsibility in complying with the referral;
- Counsel individual of the importance of the referral and follow-up method.

CHAPTER 3: REIMBURSEMENT

Medicaid Provider Enrollment

HHSC FPP contractors are required to enroll as Medicaid (Title XIX) providers with TMHP. The contractor must complete the required Medicaid provider enrollment application forms and enter into a written provider agreement with HHSC, the single state Medicaid agency. TMHP Provider Enrollment supplies these forms.

Family planning agencies are not required to enroll as a Physician Group, which includes an application for Performing Provider number. To enroll as a family planning agency, all that is required is a supervisory practitioner. The supervisory practitioner may be a physician or nurse practitioner, and it may be the same person for all clinic sites. Changes in supervisory practitioner must be reported in writing to TMHP. An application must be submitted for the new supervisory practitioner.

When enrolling as a Title XIX provider, Clinical Laboratory Improvement Amendments (CLIA) information must be provided. For public health agencies that provide limited numbers of tests, one CLIA certificate is all that is required for all clinics.

Provider Identifiers

When a contractor's Medicaid application is approved, TMHP assigns the contractor a nine-digit Texas Provider Identifier (TPI). **Contractors must have a unique TPI for each clinical service site.** To be reimbursed for FPP services, the provider must be a provider type (PT) 71 (family planning clinic) or PT 46 (federally qualified healthcare center) and bill using the associated TPI.

Contractors must submit claims to TMHP using the billing TPI where clinical services are rendered. Contractors must not provide FPP services at one clinic site and bill those services to TMHP using the TPI of a different clinic site. If an additional TPI clinic site is required, providers must contact TMHP and complete the enrollment process.

The TPI is used in conjunction with a National Provider Identifier (NPI) to identify the provider for claims processing. An NPI is a 10-digit number assigned randomly by the National Plan and Provider Numeration System (NPPES). Contractors may apply for an NPI at the NPPES website.

When a provider obtains their NPI they are required to attest to NPI data for each of their current TPI. For more information on NPI and the attestation process please visit the TMHP website.

Texas Medicaid & Healthcare Partnership and Compass 21

HHSC FPP claims are submitted to TMHP. TMHP processes claims using Compass 21, an automated claims processing and reporting system. Claims are subject to the following procedures:

- Claims are verified through a series of program edits and audits.
- Contractors receive an explanation of benefit (EOB) for each payment or denial. The EOBs are found on the Remittance and Status (R&S) report, which contractors may access electronically through the TMHP website. The report identifies paid, denied, or pending claims. If no claim activity or outstanding account receivable exists during the time period, the contractor will not receive an R&S for the week.

Texas Medicaid Provider & Procedures Manual

The *Texas Medicaid Provider & Procedure Manual* (TMPPM) includes information related to HHSC FPP claims submission such as:

- Funding sources;
- Claim billing instructions for family planning and third-party insurance;
- Sterilization consent form instructions;
- Use of the 2017 Claim Form;
- Filing deadlines;
- Claim appeals;
- FPP information;
- Diagnosis and procedure codes;
- Contraceptive devices and related procedures;
- Drugs and supplies;
- Medical counseling and education;
- Sterilization and sterilization-related procedures; and
- Additional filing resources.

In addition, Medicaid bulletins and R&S banner messages provide up-to-date claims filing and payment information. The R&S banner messages, and the TMPPM are all available on the TMHP website.

HTW Claims Pending Eligibility Determination

To verify an applicant's HTW eligibility:

- Individuals will be issued a Your Texas Benefits card with "HTW" printed in the upper right corner.
- Individuals should show their Your Texas Benefits card at the point of service delivery.
- Even with this, though, providers will need to verify the individual's eligibility. Providers can do this by going to www.YourTexasBenefitsCard.com. Or, providers can continue to call TMHP at 1-800-925-9126 or go to TexMedConnect on the TMHP website and check the member's Medicaid ID number (PCN).

Contractors must hold claims up to 45 calendar days for individuals who have applied to HTW. If an individual's HTW eligibility has not been determined after 45 calendar days, the contractor may bill the service to the FPP if the individual has a current FPP eligibility form on file. The contractor can file an FPP claim before the 45-day waiting period if a copy of the HTW program denial letter is in the individual record before filing the claim.

Sterilization Billing / Reporting

FPP contractors can receive reimbursement for vasectomy or tubal ligation/occlusion sterilization procedures as part of their family planning services. The individual may not be billed for any cost above the reimbursement rates. Individual co-pays for sterilizations must follow the contractor's established co-pay policy and may not exceed the allowable amount.

Conditions for Sterilization Procedures

Individuals receiving a vasectomy or tubal ligation/occlusion sterilization procedure must:

- be twenty-one years of age or older;
- be mentally competent; individuals are presumed to be mentally competent unless adjudicated incompetent for the purpose of sterilization;
- not be institutionalized in a correctional facility, mental hospital, or other rehabilitative facility;
- not give consent in labor or childbirth; and
- not give consent if under the influence of alcohol or drugs.

Waiting Period

- FPP contractors may provide sterilization services to their individuals after a waiting period of 30 days.
- Sterilization may be performed within 30 days but more than 72 hours after the date of the individual's signature on this consent form in the following two instances:
  - Premature delivery. The individual's expected delivery date must be completed on the sterilization consent form; or
  - Emergency abdominal surgery. The individual's circumstances must be described on the sterilization consent form.

The consent for sterilization is valid for 180 days from the date of the individual's signature.

Sterilization Consent Form

The TMPPM provides both an English and Spanish version of the Sterilization Consent Form to be used by FPP contractors. The form may be copied for use and contractors are encouraged to frequently re-copy the original form to ensure legible copies and to expedite consent validation. The TMPPM also includes detailed instructions for the completion of the Sterilization Consent Form. It is important that contractors use the most recent Sterilization Consent Form available. Additionally, it is the contractor's responsibility to ensure that the form is complete and accurate prior to submission to TMHP.

Sterilization Complications

Contractors may request reimbursement for costs associated with patient complications related to sterilization procedures. Contractors may be reimbursed for approved charges up to $1,000 per occurrence. To request reimbursement, contractors should provide the FPP with the following information:

- A copy of the R&S report showing that a sterilization procedure was performed on the individual in question;
- A narrative summary detailing the procedure performed and any related complications;
- All surgical and progress notes for the individual related to the complications of the sterilization procedure;
- The initial operative report for the sterilization surgery; and

- A completed paper 2017 Claim Form detailing the procedures for which the contractor is seeking reimbursement (list all procedures related to the complication even if they are not typically reimbursable under FPP).

Contractors may request reimbursement for costs associated with patient complications related to sterilization procedures. Contractors may be reimbursed for approved charges up to $1,000 per occurrence. To request reimbursement, contractors should provide the FPP with the following information:

- A copy of the R&S report showing that a sterilization procedure was performed on the individual in question;
- A narrative summary detailing the procedure performed and any related complications;
- All surgical and progress notes for the individual related to the complications of the sterilization procedure;
- The initial operative report for the sterilization surgery; and
- A completed paper 2017 Claim Form detailing the procedures for which the contractor is seeking reimbursement (list all procedures related to the complication even if they are not typically reimbursable under FPP).

IUD and Contraception Implant Complications

Contractors may request reimbursement for costs associated with patient complications related to IUD or contraceptive implant insertions or removals. Contractors may be reimbursed for approved charges up to $1,000 per occurrence. To request reimbursement contractors should provide the FPP with the following information:

- A copy of the R&S report showing that an IUD or contraceptive implant insertion or removal procedure was performed on the individual in question;
- A narrative summary detailing the procedure performed and any related complications;
- All surgical and progress notes for the individual related to the complication of the IUD or contraceptive implant insertion or removal procedure; and
- A completed paper 2017 Claim Form detailing the procedures for which the contractor is seeking reimbursement (list all procedures related to the complication even if they are not typically reimbursable under FPP).

Contractors may request reimbursement for costs associated with patient complications related to IUD or contraceptive implant insertions or removals. Contractors may be reimbursed for approved charges up to $1,000 per occurrence.

To request reimbursement contractors should provide the FPP with the following information:

- A copy of the R&S report showing that an IUD or contraceptive implant insertion or removal procedure was performed on the individual in question;
- A narrative summary detailing the procedure performed and any related complications;
- All surgical and progress notes for the individual related to the complication of the IUD or contraceptive implant insertion or removal procedure; and
- A completed paper 2017 Claim Form detailing the procedures for which the contractor is seeking reimbursement (list all procedures related to the complication even if they are not typically reimbursable under FPP).

Retroactive Eligibility

Retroactive eligibility occurs when an individual has applied for Medicaid coverage but has not yet been assigned a Medicaid individual number at the time of service. Individuals who are eligible for Title XIX (Medicaid) medical assistance receive three months prior eligibility to cover any medical expenses incurred during that period.

FPP Retroactive Eligibility

Any co-pay collected from an individual found to be eligible retroactively for Medicaid must be refunded to the individual. If a claim has been paid and later the individual receives retroactive Title XIX (Medicaid) eligibility, TMHP recoups/adjusts the funds paid from FPP and processes the claim as Title XIX. An FPP accounts receivable (A/R) is then established for the adjusted claim.

Note: Contractors are responsible for paying HHSC back the amount of any FPP A/R balance that may remain at the end of a state fiscal year.

The contractors' FPP R&S Report(s) will reflect the retroactive Title XIX adjustment with EOB message "Recoupment is due to Title XIX retro eligibility."

Assistance on reconciling R&S reports may be provided through the TMHP Contact Center from 7:00 a.m. to 7:00 p.m. CST, Monday through Friday at 800-925-9126. A TMHP Provider Relations representative is also available for these specific questions, as a representative can be located by region on the TMHP website.

Performing Provider Number and Retroactive Eligibility

FPP claims do not require a performing provider number for reimbursement. However, if a Title XIX retroactive eligibility claim does not have a performing provider number in a TPI format, TMHP will deny the services. A common EOB message for this specific denial is *EOB 00118: Service(s) require performing provider name/number for payment.* A request for reconsideration of claim reimbursement may be sent to TMHP through the appeal methods.

Note: The performing provider number requirement applies to all Title XIX submissions.

Claims Submitted with Laboratory Services

If a Title XIX retroactive eligibility claim includes laboratory services and the FPP contractor is not CLIA certified for the date of service on the claim, TMHP will deny the laboratory services. The Title XIX R&S report will reflect *EOB 00488 message: "Our records indicate that there is not a CLIA number on file for this provider number or the CLIA is not valid for the dates of services on the claim".*

When this occurs, the laboratory that performed the procedure(s) is responsible for re-filing laboratory charges with TMHP to receive Title XIX reimbursement. For claims past the 95-day filing deadline, the laboratory will be required to follow their Medicaid appeals process. Contractors must make arrangements with their contracted laboratory to recoup any funds paid to the laboratory for lab services for HHSC FPP individuals prior to Title XIX retro eligibility determination.

Patient Co-Pays

Title XIX does not allow providers to collect co-pays. FPP contractors must refund any co-pay collected if the individual services were billed to Title XIX.

NOTE: Contractors who have expended their awarded funds must continue to serve their existing eligible individuals and submit fee-for-service claims for services provided. It is allowable to obtain other funding to pay for these services as well as continue to charge co-pay per policy. This funding should be recorded as program income for the FPP contract.

CHAPTER 4: DATA COLLECTION AND REPORTING

Financial Reporting

VOUCHER AND REPORT SUBMISSION – Cost Reimbursement

PROGRAM INFORMATION:

Program Name: HHSC FPP
Contract Type: Cost Reimbursement
Contract Term: September 1 thru August 31

VOUCHER:

Voucher Name: HHSC State Purchase Voucher.

Submission Date: By the last business day of the month following the month in which expenses were incurred or services provided. Final voucher due within 45 days after end of the contract term.

Submit Copy to:

Name of Area	Original Signature Required		Accepted Method of Submission	# Copies
	Yes	No		
Email box designated by program		X	Email	1

Instructions: Attach B-13 to HHSC State Purchase Voucher.

NOTE: Vouchers must be submitted each month even if there are zero expenditures. Vouchers must still be submitted each month for actual expenditures of the program even if the contract limit has been reached.

_____

VOUCHER SUPPORTING DOCUMENT:

Report Name: Supporting Schedule (Form B-13) in Excel format for Family Planning Program HHSC State Purchase Voucher.

Submission Date: By the last business day of the month following the month in which expenses were incurred or services provided. Final B-13 due within 45 days after end of the contract term.

Submit Copy to:

Name of Area	Original Signature Required		Accepted Method of Submission	# Copies
	Yes	No		
Email box designated by program		X	Email	1

Instructions: Attach B-13 to HHSC State Purchase Voucher.

FINANCIAL REPORT: Financial Status Quarterly Report

Report Name: Financial Status Report (Form 269A)

Submission Date: Reports are due as follows:

Quarter 1: September – November;
Quarter 2: December – February;
Quarter 3: March – May;
Quarter 4: June – August.

Submit 30 days after the end of each quarter. The final quarterly FSR is due 45 days after the end of the contract term. The final quarter report includes all

final charges and expenses associated with the program contract. Mark as "Final".

Submit Copy to:

Name of Area	Original Signature Required		Accepted Method of Submission	# Copies
	Yes	No		
Email box designated by program	X		Email	1

Instructions: Form 269A must have an original signature (scanned email or fax accepted).

FINANCIAL REPORT: Fee-for-Service Report

PROGRAM INFORMATION:

Program Name: HHSC WHP

Contract Type: Fee-for-Service (File Furnished Voucher thru TMHP TexMed Connect/Compass 21)

Contract Term: September 1 thru August 31

FEE-FOR-SERVICE CLAIMS SUBMISSION INFORMATION:

2017 Claim Form - File Furnished Voucher thru TMHP TexMed Connect/Compass 21

Claims Filing Deadline: Within 95 days from date of service or date of 3rd party insurance EOB form. Within 45 days after the end of the contract term.

Claims Submission Entity: Texas Medicaid Healthcare Partnership/Compass 21 and/or Med-IT.

NOTE: Claims must continue to be submitted to TMHP TexMed Connect/Compass 21/Med-IT even if the contract limit has been reached.

NOTE: Appeals must be submitted within 120 days of rejection during the contract term.

All appeals must be submitted and finalized within 45 days after the end of the contract term.

Financial Status Reports (FSRs)

FPP operates using the FFS award, cost reimbursement award, and anticipated co-payments to be collected as the total budget.

The quarterly reports are due by the last business day of the month following the end of each quarter of the contract term. The final FSR, 269A, is due within 45 days after the end of the contract term, unless stipulated differently in the contract attachment following the end of the contract term. HHSC reserves the right to base funding levels, in part, upon the contractor's proficiency in identifying, billing, collecting, and reporting income, and in utilizing it for the delivery of family planning services.

Quarters for Cost Reimbursement FSR submission:

Quarter 1: September – November

Quarter 2: December – February

Quarter 3: March – May

Quarter 4: June – August

Programmatic Reporting

The FPP Promotion/Outreach Annual Report must be sent to the email box designated by program. The report is due within forty-five (45) days after the end of the contract period (October 15).

CHAPTER 5: PROGRAM PROMOTION AND OUTREACH

Contractors must promote their Family Planning Program and provide outreach within the community to:

- inform the public of the purpose of the program and available services;
- disseminate basic family planning information;
- enlist community support; and
- attract potential individuals.

To help facilitate community awareness of and access to FPP services, contractors should establish and implement planned community activities to promote their programs.

Contractors should consider a variety of program promotion and outreach strategies in accordance with organizational capacity, availability of existing resources and materials, and the needs and culture of the local community. To gauge the efficacy of program promotion and outreach activities, contractors must:

- develop an annual FPP promotion and outreach plan;
- regularly monitor plan implementation;
- evaluate the plan on an annual basis; and
- modify program promotion and outreach activities, as needed.

Contractors must submit a one-page Family Planning Program Promotion Plan for the contract period within 45 days of the contract start date.

Within forty-five days after the end of the contract period, contractors must submit a Family Planning Program Promotion/Outreach Annual Report to the email box designated by program.

SECTION V – HEALTHY TEXAS WOMEN PROGRAM POLICIES

CHAPTER 1: CLIENT ELIGIBILITY

Eligibility Guidelines

A female is eligible to receive services through HTW if she meets the following qualifications:

- is age 18-44 (women are considered age 18 on the day they turn 18 and age 44 through the last day of the month during which they turn 45);
- is age 15-17 and has a parent or legal guardian apply, renew, and report changes to her case on her behalf (women are considered age 15 the first day of the month they turn 15 and age 17 through the day before she turns 18);
- resides in Texas;
- is a United States citizen, a United States national, or legal alien;
- does not currently receive full Medicaid benefits, Children's Health Insurance Program (CHIP), or Medicare Part A or B;
- is not pregnant;
- does not have private health insurance that covers family planning services, unless filing a claim on the health insurance would cause physical, emotional or other harm from a spouse, parent, or other person; and
- has a countable household income at or below 200 percent FPL.

Other Benefits

In general, people are not eligible for HTW services if they are enrolled in another third-party payor such as private health insurance, Medicaid or Medicare, or other federal, state, or local public health care coverage that provides the same services. People with third-party insurance may be eligible for services provided by HTW if client confidentiality is a concern.

Applying for HTW

A client may apply for HTW services by completing an application form and providing documentation as required by HHSC. A female age 15 to 17 must have a parent or legal guardian apply on her behalf.

An applicant may obtain an application in the following ways:

- on HealthyTexasWomen.org;
- from a local HHSC benefits office, an HTW provider's office, or any other location that makes HTW applications available;
- on the HHSC website (Spanish);
- by calling 2-1-1;
- on YourTexasBenefits.com; or
- by any other means approved by HHSC.

HHSC accepts and processes every application received through the following means:

- in person at a local benefits office of HHSC;
- by fax;
- through the mail;
- electronically through HealthyTexasWomen.org;
- electronically through YourTexasBenefits.com; or
- by any other means approved by HHSC.

Forms can be submitted by mail or by fax to:

Healthy Texas Women
PO Box 149021
Austin, TX 78714-9021
Fax (toll-free): 1-866-993-9971

HHSC processes an HTW application within 45 days of receiving the application. Program coverage begins on the first day of the month in which HHSC receives a valid application. A client is deemed eligible to receive covered services for 12 continuous months after her application is approved. Providers and community-based organizations can help women fill out and fax their applications to HHSC for processing.

Renewal

A female, or parent or legal guardian acting on the client's behalf if she is age 15 through 17, inclusive, may renew HTW services by completing a renewal form and

providing documentation as required by HHSC. An HTW client will be sent a renewal packet during the 10th month of her 12-month certification period for HTW.

HHSC accepts and processes every renewal form received through the following means:

- in person at a local benefits office of HHSC;
- by fax;
- through the mail;
- electronically through YourTexasBenefits.com; or
- by any other means approved by HHSC.

Forms can be submitted by mail or by fax to:

Healthy Texas Women
PO Box 149021
Austin, TX 78714-9021
Fax (toll-free): 1-866-993-9971

Verifying HTW Eligibility

To verify that a woman is enrolled in HTW:

- Call the TMHP Contact Center at 1-800-925-9126
- Check online at the Texas Medicaid Provider section of www.tmhp.com
- Check online at www.YourTexasBenefits.com

Referral to Other Programs

A female who is determined ineligible for HTW may be eligible for Medicaid or FPP services. If a female is determined ineligible for HTW, the contractor should refer her to other state programs that she might be eligible for.

Determining HTW Presumptive Eligibility

HTW emphasizes the importance of proper family planning, and women's health preventative care. The goal of HTW is for women to have access to women's health services and not rely upon episodic, acute care. Presumptive eligibility is temporary eligibility that grants access to health care services (up to 90 days) when the client screens potentially eligible for services but the client's application has not been processed and approved yet by HHSC.

HTW Cost Reimbursement contractors must use a portion of their cost reimbursement funds to provide services for a limited time to a person who is

determined to be presumptively eligible for HTW and has submitted an HTW application, but a final eligibility determination has not been made by HHSC yet. Presumptive eligibility is effective for 45 days from the date the client is first seen by the medical provider. The client shall be enrolled on a presumptive eligibility basis only once in a 12-month period.

Clients seen on presumptive eligibility will be captured in the contractor's total client count only after a claim is paid. Clients seen on a presumptive basis and later determined ineligible for HTW will not be counted toward the contractor's overall client count. These claims will deny and are subject to cost reimbursement fund reimbursement as requested on the monthly voucher. Contractors should be diligent when screening clients and providing presumptive services.

HHSC has developed a screening tool and an income worksheet to help providers screen for eligibility and identify acceptable forms of proof of citizenship, identity, and income.

To verify citizenship:

- U.S. birth certificate
- U.S. citizen ID card
- Hospital record of birth
- Northern Mariana ID card
- American Indian card with classification code KIC
- Religious record of birth with date and place of birth, such as baptism record
- Affidavit from two adults establishing the date and place of birth in the United States

To verify identity:

- Current driver's license with photo
- DPS ID with photo (Texas ID card)
- Work or school ID card with photo

Documentation is not required for:

- Address
- Residency status
- Household information
- Social Security number
- Household expenses

Documentation is not required during the presumptive eligibility screening process; however, documentation will be required once the client submits an HTW application.

Verification of household composition is self-declared. Household Budget Group is determined as follows:

- Adults – The budget group consists of the applicant, applicant's spouse and mutual and non-mutual children under age 19 who are within the required degree of relationship.
- Minors – The budget group consists of parent(s), minor applicant, minor's children, and minor's siblings. Exclude parents from the minor's budget group if they are out of the household, other-released or non-related adults. The legal guardian's income will not be included in the budget group.

Adjunctive Eligibility

An applicant is considered adjunctively (automatically) eligible for HTW program services at a presumptive eligibility screening, if:

- she is receiving Temporary Assistance for Needy Families (TANF) cash or is in a TANF budget group for someone receiving TANF cash;
- she is in a Children's Medicaid budget group for someone receiving Medicaid;
- a member in her budget group receives benefits in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC); or
- she is a member of a certified Supplemental Nutrition Assistance Program (SNAP) household.

Acceptable eligibility verification documentation may include:

PROGRAM	DOCUMENTATION
WIC	WIC verification of certification letter, printed WIC-approved shopping list, or recent WIC purchase receipt with remaining balance
SNAP	SNAP eligibility letter
TANF	TANF verification certification letter

A woman may also prove income eligibility if someone in her household (such as a child) has Medicaid. Providers can verify Medicaid eligibility using TexMedConnect on the TMHP website.

Calculation of Applicant's Federal Poverty Level Percentage

The steps to determine the FPL percentage are:

1. determine the applicant's household size,
2. determine the applicant's total monthly income amount,
3. divide the applicant's **total monthly income** amount by the **maximum monthly income** amount at 100 percent FPL for the appropriate **household size**,
4. multiply by 100 percent.

The maximum monthly income amounts by household size are based on the U.S. Department of Health and Human Services federal poverty guidelines. The guidelines are subject to change around the beginning of each calendar year.

Example: Applicant has a total monthly income of $2,093 and counts three (3) family members in the household.

Total Monthly Income		**Maximum Monthly Income (Household Size of 3)**							**Actual Household FPL%**
$2,093	÷	$1,674	=	1.25	x	100%	=		125% FPL

Monthly Income Limits for Healthy Texas Women

**(based on FY 2019 FPL Guideline)*

Household Size	Monthly Income
1	$2,082
2	$2,819
3	$3,555
4	$4,292
5	$5,029
6	$5,765
7	$6,502

Date Eligibility Begins

Program coverage begins on the first day of the month in which HHSC receives a valid application. For applicants age 18 through 44, inclusive, a valid application has, at a minimum, the applicant's name, address, and signature. For applicants age 15 through 17, inclusive, a valid application has, at a minimum, the applicant's name, address, and the signature of a parent or legal guardian.

Client Fees/Co-Payments

HTW contractors may not assess a co-payment (co-pay) for HTW services from HTW clients. No HTW client shall be denied services based on an inability to pay.

Other Fees

Clients shall not be charged administrative fees for items such as processing and/or transfer of medical records, copies of immunization records, etc. Contractors can bill clients for services outside the scope of HTW allowable services, if the service is provided at the client's request, and the client is made aware of her responsibility for paying for the charges.

Continuation of Services

Contractors who have expended their awarded HTW funds are required to continue to serve their existing HTW clients.

If other funding sources are used to provide HTW services, the funds must be reported as non-HHSC funds on the Supporting Schedule (Form B-13) for the monthly voucher and the quarterly Financial Status Report (FSR or Form 269a).

Auto-Enrollment from Medicaid for Pregnant Women

Per TAC Rule §382.7, (f), HHSC automatically enrolls women, ages 18 through 44, in HTW upon termination of Medicaid for Pregnant Women coverage to provide continuity of care. A month prior to a woman's Medicaid for Pregnant Women benefits ending, HHSC staff determine eligibility for any other Medicaid program or CHIP. If the woman is determined ineligible for Medicaid or CHIP, and does not have other creditable health coverage, she will be certified for HTW. HTW coverage begins the first day following the termination of a woman's Medicaid for Pregnant Women coverage. HHSC sends a woman who is auto-enrolled into the HTW program a letter in the mail notifying her of her HTW coverage and gives her the option to not participate in the program.

CHAPTER 2: CLINICAL POLICY

This chapter describes the requirements and recommendations for HTW contractors pertaining to the delivery of direct clinical services to patients. In addition to the requirements and recommendations found within this section, contractors should develop protocols consistent with national evidence-based guidelines appropriate to the target population.

All providers must offer the following core family planning services:

- Contraceptive services (pregnancy prevention and birth spacing)
  - Intrauterine devices (IUDs), contraceptive implants, oral contraceptive pills, three-month (medroxyprogesterone) injections, sterilizations, etc.
- Pregnancy testing and counseling
- Health screenings
  - Cervical cancer screening (Pap smears, etc.)
  - Screening for hypertension, diabetes, and elevated cholesterol
- Preconception health (e.g., screening for obesity, smoking, and mental health)
- Sexually transmitted infection (STI) services
  - Chlamydia and gonorrhea screening and treatment
  - HIV screening

Covered Services

HTW seeks to promote the general and reproductive health of Texas women by providing safe and effective family planning and certain primary care services to women age 15 through 44 who meet program eligibility requirements.

The following services are covered under the HTW program:

- Annual family planning and preventive healthcare visit
- Contraceptive services, all methods except elective abortion and emergency contraception, including necessary follow-up and surveillance
- Preconception care
- Certain screening, diagnostic, and treatment services, as indicated:
  - Pregnancy testing
  - Screening, diagnosis, and treatment of Cervical Intraepithelial Neoplasia, diagnosis of cervical cancer

  - Screening and outpatient treatment of sexually transmitted diseases and infections (STD/STI)
  - HIV testing
  - Breast cancer screening and diagnosis
- Recommended immunizations
- Screening and treatment of postpartum depression
- Diabetes screening and treatment
- Hypertension screening and treatment
- Screening and treatment of elevated cholesterol

Requirement for Documentation of Reproductive Health Services

The guiding principle of the HTW program is to improve the reproductive health of women to ensure that every pregnancy and every baby are healthy. At each patient encounter, including encounters for treatment of other conditions (e.g., diabetes, follow up of abnormal Pap smear), the provider must educate the patient on how the service being provided relates to reproductive health or contraception, and this must be documented in the patient record. Providers are encouraged to take the opportunity provided by each subsequent encounter to reinforce or build on the counseling provided in previous encounters. The following examples are provided for illustration purposes only:

- If the patient is being seen for treatment of a covered chronic health condition such as hypertension or diabetes, the provider might explain briefly that control of a chronic disease such as hypertension prior to becoming pregnant can substantially reduce the risk of complications if a pregnancy occurs, and that this is important even for women who are using contraception or not actually trying to become pregnant because many pregnancies are unplanned and all contraceptive methods carry some risk of pregnancy.
- At a subsequent encounter for treatment of the same chronic condition, the provider might discuss how pregnancy might affect the course of the condition (e.g. how medication requirements might change or what complications she might be at risk for).
- If the patient is being seen for another diagnostic or preventive health service (e.g. influenza immunization, follow-up of an abnormal Pap smear), the provider might explain briefly why it is important to prevent influenza in

a possible pregnancy or how prevention of cervical cancer relates to overall reproductive health.
- If the patient is being seen for contraceptive surveillance, no additional documentation is required beyond that for the contraceptive service.
- For a patient who has undergone sterilization, this counseling and documentation are not required when receiving covered services.

Client Health Record and Documentation of Patient Encounters

Providers must ensure that a patient health record (medical record) is created for every client who obtains clinical services.

All patient health records must be:

- A complete, legible, and accurate documentation of all clinical encounters, including those that take place by telephone.
- Written in ink without erasures or deletions; or documented in the Electronic Health Record (EHR) or Electronic Medical Record (EMR).
- Signed by the provider making the entry, including name of the provider, provider title, and date for each entry.
  - Electronic signatures are allowable to document provider review of care.
  - Stamped signatures are not allowable.
- Readily accessible to ensure continuity of care and availability to patients.
- Systematically organized to allow easy documentation and prompt retrieval of information.

The client health record must include:

- Client identification and personal data, including financial eligibility.
- The client's preferred language and method of communication.
- Client contact information, including the best way and alternate ways to reach the client, to ensure continuity of care, confidentiality, and compliance with HIPAA regulations.
- A patient problem list, updated as needed at each encounter, indicating significant illnesses and medical conditions.
- A complete medication list, including prescription and nonprescription medications, as well as dietary supplements, updated at each encounter.

- A complete listing of all medication allergies and adverse reactions, and other allergic reactions, displayed in a prominent place, and confirmed or updated at each encounter; if the patient has no known allergies, this must be properly noted.
- Documentation of the client's past medical history to include all serious illnesses, hospitalizations, surgical procedures, pertinent biopsies, accidents, exposures to blood products, and mental health history.
- A record or history of immunizations, including immunity to rubella based on a history of vaccine or documented serology testing.
- A patient health risk survey and assessment, including past and current tobacco, alcohol, and substance use/abuse, domestic and/or intimate partner violence and/or abuse (for any positive result, the client must be offered referral to a family violence shelter in compliance with Texas Family Code, Chapter 91), occupational and environmental hazard exposure, environmental safety (e.g., seat belt use, car seat use, bicycle helmets, etc.), nutritional and physical activity assessment, and living arrangements (e.g. homelessness or risk of homelessness), updated as appropriate at each encounter.
- At each encounter, an encounter-relevant history and physical examination pertinent to the patient's reason for presentation, with appropriate laboratory and other studies as indicated.
- A plan of care, updated as appropriate, consistent with diagnoses and assessments, which in turn are consistent with clinical findings.
- Documentation of recommended follow-up care, scheduled return visit dates, and follow-up for missed appointments.
- Documentation of informed consent or refusal of services, to include at a minimum:
  - A general consent for treatment
  - Verbal or written consent for HIV testing, or patient refusal of testing
  - Sterilization consent form, if applicable
  - A completed Texas Medical Disclosure Panel Consent form for any surgical services provided, if applicable
  - For required or recommended services refused or declined by the patient, documentation of the service offered, counseling provided, and the patient's decision to decline
  - Note the following special considerations for adolescent (age 17 and younger) consent requirements, as required by the Texas Family Code Chapter 32 and Chapter 151.

- Adolescents are required to have consent from a parent or guardian prior to receiving certain medical services; proof of parental consent must be included in the minor patient's medical record when required.
- Adolescents are not required to have parental consent to receive pregnancy-related services (including pregnancy testing), sexually transmitted disease/infection (STD/STI) and HIV testing, or STD/STI treatment.
- Documentation of client counseling and education, with attention to risks identified in the health risk assessment.
- At every client visit, the record must be updated as appropriate, and the reason for the visit, any assessment made, and service provided must be documented.

Initial Clinical Visit

At the initial clinical visit or an early subsequent visit, a comprehensive health history must be taken, to include the following (in addition to the elements required for the Client Health Record above):

- Reason for the visit and current health status;
- Review of systems with documentation of pertinent positives and negatives;
- A reproductive health history, to include menstrual history, complete obstetrical history, sexual activity history (including number and gender of partners, contraceptive practices, sexually transmitted infection/sexually transmitted disease [STI/STD] and HIV history and risk factors, whether currently sexually active), and reproductive life plan;
- Cervical and breast cancer screening history, noting any abnormal results and treatment, and dates of most recent testing;
- Other history of gynecological, genital, and/or urological conditions; and
- Family health and genetic history.

At every subsequent visit, including the annual primary health care and problem visits, the record must be updated as appropriate, and the reason for the visit and current health status documented.

Annual Comprehensive Family Planning Visit, Physical Examination and Testing

The annual family planning visit offers an excellent opportunity for providers to address issues of wellness and health risk reduction as well as addressing any

current findings or patient concerns. The annual visit must include an update of the person's health record as described in the Client Health Record section above, as well as appropriate screening, assessment, counseling, and immunizations based on the person's age, risk factors, preferences, and concerns.

All clients must undergo a physical examination annually as part of the family planning visit. This can be deferred to a later date if the patient's current history and health status do not suggest issues requiring more urgent examination. However, the annual physical examination should not be deferred longer than six months, unless the clinician identifies a compelling reason for extended deferral. Such reason must be documented in the client record. Any breast or pelvic examination should be performed only with the consent of the patient. Clients must be offered a suitable method of contraception, such as oral contraceptives, without delay even if the physical examination is put off temporarily or an otherwise asymptomatic person declines any or all components of the examination.

It is recommended that the family planning visit include all of the following components, at least annually, in addition to any other appropriate elements as suggested by history and presenting signs and symptoms (all findings, including tests, results, and patient notification, should be documented in the medical record, as well as patient refusal or other reason for not testing or performing a specified part of the examination):

- Measurement of height, weight, and blood pressure (BP); screening for hypertension.
- Calculation of body mass index (BMI) with assessment for underweight, overweight, or obesity, with counseling (if indicated) on achieving and maintaining a healthy body weight. An adult BMI calculator and a BMI calculator for children and teens are available from the Centers for Disease Control and Prevention.
- Clinical breast examination, breast cancer risk assessment, and breast cancer screening as appropriate based on patient's age, risk, and preferences.
- Counseling on breast awareness and advice to report any symptom or sign that is concerning to the patient.
- Screening for cervical cancer beginning at 21 years of age, regardless of sexual history, and continuing as indicated based on the person's age, prior test results, and treatment history.

- Pelvic examination (for all consenting patients 21 years and older; only if indicated by the medical history in consenting patients less than 21 years of age) to include the following elements:
  - Visual examination of the external genitalia, vaginal introitus, urethral meatus, and perianal area;
  - Speculum examination of the cervix and vagina; and
  - Bimanual examination of the cervix, uterus, and adnexa; and when indicated, rectovaginal examination.
- Other examination as indicated by history, signs and symptoms, and patient concerns (e.g. thyroid, heart, lungs, abdomen, etc.).
- Diabetes screening as appropriate for age and risk factors.
- Other appropriate screening or testing as indicated by age, risk factors, history, physical findings, and patient concerns:
  - Sexually transmitted infections;
  - Pregnancy testing, available on-site (If the pregnancy test is positive, the patient must be given information on good health practices during pregnancy and given or referred for appropriate physical evaluation and initiation of prenatal care, preferably within 15 days.);
  - Rubella immunity testing in women of reproductive age if the status cannot be determined by history or previous testing;
  - Cholesterol and/or serum lipid testing;
  - Thyroid stimulating hormone; and
  - Other testing if indicated.
- Appropriate family planning counseling and services.
- Preconception care as appropriate.
- *Immunizations as indicated.
- Healthy lifestyle interventions and counseling as indicated based on age, risk factors, and client interest and receptiveness.

*Healthcare providers can voluntarily participate in DSHS' Adult Safety Net (ASN) vaccine program, which provides vaccines at no cost.

Counseling and Education

All clients must receive accurate patient-centered education and counseling in their preferred language, presented in a way they are able to understand and to demonstrate their understanding, and documented in the medical record. The intent of patient education is to enable the client to understand the range of

available services and how to access them, to make informed decisions about family planning, to reduce personal health risk, and to understand the importance of recommended tests, health promotion, and disease prevention strategies.

Specific clinical policies must be in place to address counseling and other services provided to adolescents age 17 and younger, to include the following, at a minimum:

- Counseling of adolescents must include the following topics, and comply with the child abuse and neglect reporting requirements of the Texas Family Code, Chapter 261:
  - All medically approved methods of contraception, including abstinence;
  - Prevention of STD/STIs and HIV;
  - Domestic, partner, dating, and family violence and the offer of assistance as needed; and
  - Recognition and avoidance of sexual coercion.
- Counseling and clinical services to adolescents must be expedited so that appointments are made available as soon as possible.
- Adolescents must be assured that their privacy and confidentiality will be protected within the parameters of applicable law, including the Health Insurance Portability and Accountability Act (HIPAA), Texas Family Code, Chapter 32, and Section II Chapter 2 (Consent)of this policy manual.

Details of appropriate educational interventions are included in each section of this clinical policy manual. In addition, links are provided to information of use to patients and educators at the end of most sections.

Requirements for Policies to Ensure Appropriate Follow-up and Continuity of Care

Providers must develop and maintain policies and procedures to ensure proper timely follow-up and continuity of care, to include, at a minimum:

- Tracking pending tests until results are reviewed by provider and patient is notified of results and recommended follow-up;
- Documentation of all tests and results in the client health record;
- A mechanism to inform clients promptly of test results that protects the patient's privacy and confidentiality while supporting and promoting timely, appropriate follow-up;

- A mechanism to track patient compliance with recommended follow-up care, schedule return visits, and follow up on missed appointments; and
- A process to ensure compliance with all applicable state and local laws for disease reporting.

Before a patient is considered lost to follow-up, the contractor must make at least three documented separate attempts to contact the patient, using an accelerated protocol, where subsequent attempts involve a more intensive effort to contact the patient. An example might be a telephone call on the first attempt, a letter by regular mail on the second, and a certified letter on the third. Providers should develop processes that are adapted to circumstances of the population they serve, and adapt their usual processes as needed based on their knowledge of the circumstances and preferences of the person they are attempting to contact.

Problem Visits

For all problem visits, the following elements must be documented in the medical record:

- Reason for the visit;
- Appropriate interval medical history and focused history relevant to the problem reported; and
- Relevant physical examination and testing as indicated, as well as an assessment and treatment prescribed.

Referrals

When a client is referred to another provider of services for consultation or continuation of care, the chart must reflect a record of the purpose for the referral, the name of the provider consulted or referred to, counseling of the patient regarding the purpose of the referral and answering any questions the patient has about the referral. Pertinent patient information and appropriate portions of the medical record must be provided to the referral clinician, and this must also be documented in the medical record. The results of the consultation or referral must be followed up on and documented in the medical record.

Contractors must maintain a written policy reflecting these requirements for referral activities.

Prescriptive Authority Agreements

When services are provided by Advanced Practice Registered Nurse(s) and/or Physician Assistant(s), it is the responsibility of the contractor to ensure that a properly executed prescriptive authority agreement (PAA), as required by Texas Administrative Code, Title 22, Part 9, Chapter 193, is in place for each such provider. This is true whether the provider is employed by the contractor or is providing services by subcontract with or referral by the contractor. The PAA must meet all the requirements delineated in the Texas Occupations Code, Chapter 157, including, but not limited to, the following minimum criteria:

- Be in writing, signed, and dated by the parties to the agreement;
- Include the name, address, and all professional license numbers of all parties to the agreement;
- State the nature of the practice, practice locations, or practice settings;
- Identify the types or categories of drugs or devices that may be prescribed, or the types or categories of drugs or devices that may not be prescribed;
- Provide a general plan for addressing consultation and referral;
- Provide a plan for addressing patient emergencies;
- Describe the general process for communication and sharing of information between the physician and the advanced practice registered nurse or physician assistant to whom the physician has delegated prescriptive authority related to the care and treatment of patients;
- If alternate physician supervision is to be utilized, designate one or more alternate physicians who may:
- Provide appropriate supervision on a temporary basis in accordance with the requirements established by the prescriptive authority agreement and the requirements of this subchapter; and
- Participate in the prescriptive authority quality assurance and improvement plan meetings required under this section; and
- Describe a prescriptive authority quality assurance and improvement plan and specify methods for documenting the implementation of the plan that includes the following:
- Chart review, with the number of charts to be reviewed determined by the physician and advanced practice registered nurse or physician assistant; and
- Periodic face-to-face meetings between the advanced practice registered nurse or physician assistant and the physician at a location determined by

the physician and the advanced practice registered nurse or physician assistant.

The PAA need not describe the exact steps that an advanced practice registered nurse or physician assistant must take with respect to each specific condition, disease, or symptom. The PAA and any amendments must be reviewed at least annually, dated, and signed by the parties to the agreement. A copy of the current PAA must be maintained on-site where the advanced practice registered nurse or physician assistant provides care.

Standing Delegation Orders

When services are provided by unlicensed and licensed personnel, other than advanced practice nurses or physician assistants, whose duties include actions or procedures for a population with specific diseases, disorders, health problems or sets of symptoms, the clinic must have written standing delegation orders (SDOs) in place. SDOs are distinct from specific orders written for a particular provider. SDOs are instructions, orders, rules, regulations or procedures that specify under what set of conditions and circumstances actions should be instituted.

The SDOs delineate under what set of conditions and circumstances an RN, LVN, or non-licensed healthcare provider (NLHP) may initiate actions or tasks in the clinical setting and provide authority for use with patients when a physician or advance practice provider is not on the premises, and/or prior to being examined or evaluated by a physician or advanced practice provider. Example: SDO for assessment of blood pressure/blood sugar which includes an RN, LVN or NLHP that will perform the task, the steps to complete the task, the normal/abnormal range, and the process of reporting abnormal values.

Other applicable SDOs when a physician is not present on-site may include, but are not limited to:

- Obtaining a personal and medical history;
- Performing an appropriate physical exam and the recording of physical findings;
- Initiating/performing laboratory procedures;
- Administering or providing drugs ordered by voice communication with the authorizing physician;
- Providing pre-signed prescriptions for:

  - oral contraceptives;
  - diaphragms;
  - contraceptive creams and jellies;
  - topical anti-infective for vaginal use; or
  - antibiotic drugs for treatment of STI/STDs.
- Handling medical emergencies – to include on-site management as well as possible transfer of the patient;
- Giving immunizations; or
- Performing pregnancy testing.

The SDOs must be reviewed, signed, and dated by the supervising physician who is responsible for the delivery of medical care covered by the orders and other appropriate staff, at least annually and maintained on-site.

References

- American Academy of Family Physicians (2017). Summary of recommendations for clinical preventive services. AAFP Policy Action Order No. 1968. Available at: http://www.aafp.org/dam/AAFP/documents/patient_care/clinical_recommendations/cps-recommendations.pdf
- American College of Obstetricians and Gynecologists (2012). Committee opinion 755 Well-woman visit. *Obstet Gynecol* 120: 421-424. Available at: http://www.acog.org/Resources_And_Publications/Committee_Opinions/Committee_on_Gynecologic_Practice/Well-Woman_Visit
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- Centers for Disease Control and Prevention. Clinical content of care for men website. Available at: https://www.cdc.gov/preconception/men.html
- Centers for Disease Control and Prevention (2014). Providing quality family planning services. *MMWR* 63(4). Available at: http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf
- Centers for Disease Control and Prevention (2016). Update: Providing quality family planning services - Recommendations from CDC and the U.S. Office of Population Affairs, 2015. *MMWR* 65(9); 231-234. Available at: https://www.cdc.gov/mmwr/volumes/65/wr/mm6509a3.htm

- Centers for Disease Control and Prevention. Immunization schedules website. Available at: http://www.cdc.gov/vaccines/schedules/

Family Planning and Contraceptive Services

Reproductive Life Plan

Providers should encourage all clients to develop a reproductive life plan, which is an outline of each person's immediate and future plans for having children. Questions such as the following can be useful in helping clients to develop the plan:

- Do you have children now?
- Do you desire to have (more) children?
- How many children would you like to have and when?
- Of course, providers and clients should understand that such plans can change with time. Providers should take the client's stated plan into account in counseling on contraceptive and family planning services.
- If the client is sexually active and does not desire pregnancy, offer contraceptive services.
- Provide pregnancy testing and counseling to any woman who may be pregnant or who requests such testing. Initiate or provide referral for prenatal services if positive.
- If pregnancy is currently desired and the woman is not pregnant, offer services to help her and her partner to achieve a safe and healthy pregnancy.

Contraceptive Counseling and Education

At each encounter for services, clients must receive patient-centered counseling and education to enable them to make informed decisions about family planning, including information on preventing STD/STIs and HIV, the results of the physical examination and other testing, method-specific counseling as described below, and other counseling as indicated by the history and clinical evaluation.

Providers must offer clients a wide array of contraceptive options appropriate for the person's health status and reproductive plan. A six-step approach that seeks to engage the client in the decision-making process while addressing personal and cultural preferences will improve client satisfaction and the likelihood that the selected method will be used correctly and consistently.

1. Establish and maintain rapport with the client. Some ways to do this include:
   a. Ask open-ended questions.
   b. Ensure confidentiality and privacy and explain how confidential information may be used.
   c. Listen to and observe the client.
   d. Encourage questions and provide culturally sensitive answers that demonstrate knowledge of the subject matter in language the client understands.
2. Obtain social and clinical information from the client to include the following:
   a. Health history
   b. Current reproductive life plan
   c. Contraceptive experience and possible preferences
   d. Assessment of sexual health:
      i. Past and current contraceptive practices
      ii. Partner history (e.g., number, sex, whether concurrently monogamous)
      iii. Current and past STD/STI prevention (e.g., limiting partners, use of condoms, barriers to condom use, consistency of use)
      iv. Prior treatment for and possible exposure to STD/STIs
3. Work interactively with the client to choose the most appropriate contraceptive method.
   a. Educate the client about all contraceptive methods that are safe and appropriate for her.
   b. Providers should counsel patients on the relative effectiveness of methods, correct use of methods, potential non-contraceptive benefits (e.g., reduced risk of iron-deficiency anemia with combination hormonal contraceptives), and method side effects, working with the person or couple to select the method that best meets their needs and wishes.
   c. Clients should be informed that contraceptive methods other than condoms provide no protection from STD/STIs, including HIV; and that condoms used correctly and consistently do help to reduce the risk of STD/STIs, including HIV.
   d. Help the client to identify barriers to correct contraceptive method use and develop solutions to overcome barriers.
4. Perform a physical evaluation appropriate to the method chosen, when warranted. In most cases, no physical examination or laboratory testing is necessary prior to initiating a contraceptive method.

a. Blood pressure should be recorded prior to starting combination hormonal contraception.
b. Current pregnancy status should be determined at the time of service for any woman receiving contraceptive services, but routine pregnancy testing is not necessary if it is possible to be reasonably certain that she is not pregnant. A provider may be reasonably certain that a woman is not currently pregnant if she has no signs or symptoms of pregnancy (either intrauterine or ectopic) and meets at least one of the following criteria:
   i. < 7 days since the start of a normal menses
   ii. No sexual intercourse since the beginning of the last normal menses
   iii. Has been using a reliable method of contraception correctly and consistently
   iv. < 7 days since a spontaneous or induced abortion
   v. < 4 weeks postpartum
   vi. < 6 months postpartum, amenorrhoeic since delivery, and exclusively or almost exclusively breast feeding (at least 85 percent of infant feedings are breast feedings)
c. Weight assessment is not necessary before initiating a contraceptive method because obesity alone is not a contraindication to any method. However, a baseline weight measurement may aid in assessing the possible effect of a chosen method on weight change.
d. Certain tests and components of the physical examination may provide logistical, economic or emotional barriers to contraceptive access or acceptance for some women. In most cases, many of these interventions can be safely delayed, or avoided altogether if necessary, to enable a healthy person to initiate an appropriate and preferred method (although there may be other healthcare-related indications for the interventions). The following tests and examinations are not necessary prior to initiating a contraceptive method:
   i. Pelvic examination, except when fitting a diaphragm or inserting an IUD
   ii. Cervical, breast, or other cancer screening
   iii. HIV screening
   iv. Laboratory testing for hemoglobin, glucose, lipid, or liver enzyme levels; or for thrombogenic mutations
   v. Any physical examination prior to distributing condoms

5. Once a method of contraception is selected, the provider should provide counseling on correct and consistent use, assist the client to develop a plan for correct use and follow-up, and confirm the client's understanding. Certain considerations may increase the likelihood of correct and consistent use.
   a. Ideally, the method should be dispensed on-site and started at the time of the visit (rather than waiting for the next menses), if the provider can be reasonably certain the woman is not pregnant (see item 4.b above for criteria to determine with reasonable certainty that a woman is not currently pregnant).
   b. Multiple cycles (ideally a full year's supply) of oral contraceptive pills, the patch, or the ring should be prescribed or provided to reduce the number of return visits necessary.
   c. Make condoms available easily and at no cost to the client.
   d. If the client's chosen method is not available on-site or immediately, provide another method on the day of the visit to be used until the chosen method can be started.
6. Finally, help the client develop a plan for correct and consistent use of the chosen method and provide a plan for follow-up.
   a. Explore possible reasons for incorrect or inconsistent use and help develop strategies to deal with these. For example:
      i. Suggest a daily text message or a sign on the bathroom mirror to routinize daily pill taking.
      ii. Discuss ways to ensure timely return for injections.
      iii. Discuss side effects, a common reason for method discontinuation, and ways to deal with these.
   b. Create a follow-up plan with the client, taking into account the client's unique needs and perceived risk of method lapse or discontinuation.
   c. Confirm the client's understanding of the information given and document this in the medical record.
      i. The teach-back method, in which the client demonstrates understanding of the information by repeating back her understanding of the messages received, is a good way to confirm understanding and to increase retention of the information received.
      ii. Provide counseling with teach-back of the following topics, at a minimum:
         a) Real-world method effectiveness
         b) Correct method used and common side effects

c) Back-up contraceptive methods, including issues related to discontinuation of the chosen method
d) Whether or not the method protects against STD/STIs
e) Signs of rare, but serious, complications, and what to do if any of these signs occurs
f) How to seek urgent or emergency care, including a 24-hour emergency telephone number
g) When to return for follow-up

Relative Method Effectiveness

The following contraceptive methods and services necessary to provide them are approved for reimbursement under HTW. Providers must make each method available either on-site or by referral. Relative method effectiveness (range of effectiveness for 100 women using the method for 1 year) is indicated in parentheses, if reported values are available. Actual effectiveness depends on correctness and consistency of use.

- Extremely effective (> 99 percent effective):
  - Total sexual abstinence
  - Contraceptive implant
  - Intrauterine device
  - Male or female sterilization

- Less effective (ranges of effectiveness are shown where the source used provides a range or multiple sources provide differing rates or ranges):
  - Lactational amenorrhea (98-99 percent; must be < 6 months postpartum, amenorrhoeic, and providing 85-100 percent of infant feedings as breast feedings)
  - Progestin injection (Depo-Provera, 94-97 percent)
  - Hormonal contraceptive pills (91-92 percent)
  - Hormonal contraceptive patch (91-92 percent)
  - Vaginal ring (91-92 percent)
  - Diaphragm (82-88 percent)
  - Male condom (82-85 percent)
  - Female condom (79 percent)
  - Withdrawal ("pulling out," 78-82 percent)
  - Cervical cap (71-86 percent)
  - Fertility awareness ("rhythm," 75-76 percent)

- Spermicide (71-72 percent)
- Sponge (68-88 percent, more effective in parous women)

Long-Acting Reversible Contraceptive (LARC) Methods

Because of their safety, reversibility, ease of use, and very high real-world effectiveness, providers are encouraged to make LARC agents and devices (i.e. the intrauterine device and the subdermal contraceptive implant) available to all clients who are candidates for their use. See the web page Long-Acting Reversible Contraception Program from the American Congress of Obstetricians and Gynecologists for information and resources on the use of LARCs.

For more information on implementing a program to provide LARCs, see the Texas LARC Toolkit on the Healthy Texas Women website.

Consent for Sterilization

For clients who choose sterilization, two consent forms are required to be signed by the patient after counseling on method-specific risks and benefits is provided and all the patient's questions have been answered:

- The Sterilization Consent Form must be signed by the patient at least 30 days and not more than 180 days prior to the procedure. An exception is made if the patient undergoes emergency abdominal surgery or preterm birth, in which case, the form must be signed at least 72 hours before the sterilization procedure (and at least 30 days prior to the expected date of delivery if preterm birth is the reason for the exception).
  A Texas Medical Disclosure Panel Consent for the surgical procedure by which sterilization will be performed must be signed by the patient after full disclosure of the risks and possible benefits is provided and all the patient's questions are answered.

Note on Abortions:

- Per the 2018-2019 General Appropriates Act, abortion is not considered a method of family planning and no state funds appropriated to the department shall be used to pay the direct or indirect costs (including overhead, rent, marketing, phones and utilities) of abortion procedures provided by contractors.
- Emergency contraceptive pills (EC or ECP) and related provider services are not reimbursable under the HTW program.

References

- American College of Obstetricians and Gynecologists. (2015.) Committee Opinion No. 642: Increasing access to contraceptive implants and intrauterine devices to reduce unintended pregnancy. *Obstet Gynecol, 126*(4), e44-e48. Available at: https://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Gynecologic-Practice/Increasing-Access-to-Contraceptive-Implants-and-Intrauterine-Devices-to-Reduce-Unintended-Pregnancy
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Resources for Patients and Educators

- Centers for Disease Control and Prevention. Contraception webpage. Provides information for patients and educators on birth control methods and relative effectiveness; includes a printable graphic poster showing various methods and estimates of pregnancy risk with each. Available at: https://www.cdc.gov/reproductivehealth/contraception/index.htm

Resources for Providers

- American Congress of Obstetricians and Gynecologists. Long-acting reversible contraception program web page. Provides information, clinical guidance, and educational materials on Long-acting reversible contraceptives [LARC]. Available at: https://www.acog.org/About_ACOG/ACOG_Departments/Long_Acting_Reversible_Contraception

Preconception Services

The goal of preconception care is optimizing the health of every woman to lay the foundation for the best possible outcome of every pregnancy. Because almost half of all pregnancies in the United States are unplanned, and most pregnancies occur in women who did not have a specific preconception care visit prior to becoming pregnant, providers should keep preconception care in mind at every encounter with a woman of childbearing potential.

Good preconception care incorporates all components of general health care as described elsewhere in this manual. Attention should be paid to the following components:

- Optimization of known chronic medical conditions, such as diabetes, hypertension, thyroid disease, epilepsy, asthma, etc. For example:
  - A normal hemoglobin A1c prior to and early in pregnancy can substantially reduce the risk of birth defects in the offspring of mothers with Type 1 and Type 2 diabetes.
  - Women with hyperthyroidism or hypothyroidism should be treated as necessary to ensure that they are euthyroid prior to and during pregnancy to reduce the risk of miscarriage and preterm birth.
  - Women with a history of phenylketonuria should be counseled on the need to follow a low-phenylalanine diet before and during pregnancy to reduce the risk of birth defects and serious developmental delay in the offspring.
- Screening as indicated for any conditions that may be undiagnosed
- Confirming that immunizations are current
- Medications (prescription and nonprescription) and potential radiation exposure in early pregnancy

  - In general, the lowest effective dose of necessary medications is preferred, but patients should be cautioned against discontinuing or changing medications without first consulting their doctor, because an untreated or incompletely treated medical condition may pose greater risk to the fetus and mother than the medication prescribed.
  - Some known teratogenic medications include warfarin, valproic acid, carbamazepine, isotretinoin, and angiotensin-converting enzyme inhibitors.
  - For more patient and provider information on risk associated with specific exposures to medications and other environmental factors, consult the web site of the Organization of Teratology Information Specialists.
- Prevention of STD/STIs
- Nutrition and food insecurity
- Occupational and environmental exposures to health risks and teratogens
- Tobacco and substance use, other high-risk behaviors
- Family medical history and genetic risk
- Domestic, intimate, and partner violence
- Social issues, such as homelessness
- Mental health

References

- American Academy of Pediatrics/American College of Obstetricians and Gynecologists. *Guidelines for Perinatal Care 7th Ed*. (2012). Ch. 5, pp. 95-106.
- American College of Obstetricians and Gynecologists. Committee opinion 313: The importance of preconception care in the continuum of women's health care. Obstet Gynecol (2005). 106: 665-666. Available at: https://www.ncbi.nlm.nih.gov/pubmed/16135611
- Centers for Disease Control and Prevention. Recommendations to improve preconception health and health care – United States. *MMWR* (2006). 55(RR06): 1-23. Available at: http://www.cdc.gov/mmWR/PDF/rr/rr5506.pdf
- Organization of Teratology Information Specialists. MotherToBaby: Medications & more during pregnancy & breastfeeding. Available at http://mothertobaby.org/fact-sheets-parent/ (provides information for patients and health care providers on teratogenic risk of drugs and other exposures in pregnancy)

Resources for Patients and Providers

- American Society for Reproductive Medicine. http://www.reproductivefacts.org/ (information for patients on a variety of topics related to fertility and infertility)
- Centers for Disease Control and Prevention. Content of care for women website. Available at: https://www.cdc.gov/preconception/women.html
- Centers for Disease Control and Prevention. Preconception health and health care web site. Contains links to resources for patients, providers, and patient educators on planning for a healthy pregnancy. Available at http://www.cdc.gov/preconception/index.html

Cervical Cancer Screening

Note that the summary of cited guideline recommendations provided in this section reflects the ages of eligibility for HTW and does not include guideline recommendations for patients outside this range.

In writing this summary, guidelines from a variety of medical specialty organizations and US government agencies were reviewed. Where slight divergence was found among guidelines from different organizations, an attempt was made to synthesize the recommendations so that all recommendations are represented cohesively in the summary below.

The majority of cases of cervical cancer occur in women who have never had screening or have had inadequate screening. It is estimated that half of women who receive a diagnosis of cervical cancer have never had cervical cytology testing, and an additional 10 percent have not had screening in the 5 years prior to the diagnosis of cancer. Providers are encouraged to implement and participate in programs aimed at increasing the percentage of women in their communities who receive indicated cervical cancer screening.

General Considerations

- Cervical cancer screening should begin at 21 years of age. Except for women who are infected with HIV or otherwise immunocompromised, screening should not be performed prior to age 21.

- Women with the following risk factors are at higher risk and may require more frequent screening than described in this policy manual, which is intended for women of average risk:
  - Women with HIV infection or other reason for immunocompromise (e.g. history of solid organ transplant)
  - History of in utero exposure to diethylstilbestrol
  - Prior treatment for CIN 2, CIN 3, or cervical cancer.
- Either liquid-based or conventional (PAP smear) methods of cervical cytology are acceptable.
- When human papillomavirus (HPV) testing is performed, it should include testing to detect only those HPV genotypes with known carcinogenic potential, so-called high-risk HPV genotypes. Testing for low-risk genotypes, those without demonstrated carcinogenic potential, should not be performed. References to HPV testing in the remainder of this topic section are for high-risk HPV only.
- Screening guidelines should be applied to women who have received the HPV vaccine in the same way as for women who have not received the vaccine.

Screening Frequency and Response to Abnormal Findings

- Routine annual cervical cancer screening is not appropriate for women of average risk in any age group.
- Women 21-29 years of age should undergo screening every 3 years by cervical cytology testing alone, with reflex human papillomavirus (HPV) testing when cytology reveals atypical squamous cells of undetermined significance (ASCUS). Co-testing (cervical cytology combined with routine HPV testing) should not be performed in women younger than 30 years of age.
- For women 25-29 years of age, the FDA-approved primary HPV screening test may be considered as an alternative to cytology-based screening, although cytology alone with reflex HPV testing when cytology reveals ASCUS is recommended by major professional society guidelines. If the primary HPV test is to be used for screening, it should be done according to interim guidance provided by the American Society for Colposcopy and Cervical Pathology and the Society of Gynecologic Oncology.
- For women 30 to 44 years of age, published guidelines recommend screening by any of three methods:
  - Co-testing (combined cervical cytology and HPV testing) every 5 years

  - Cervical cytology testing alone, with reflex HPV testing when cytology reveals ASCUS, every 3 years
  - Screening with the FDA-approved primary HPV screening test every five years; if the primary HPV test is to be used for screening, it should be done according to interim guidance provided by the American Society for Colposcopy and Cervical Pathology and the Society of Gynecologic Oncology.
- It is reasonable to perform annual cervical cytology testing in women with in utero exposure to diethylstilbestrol.
- For any patient with an abnormal result, further testing and follow-up should be dictated by findings, diagnosis, and current evidence-based guidelines, such as that of the American Society for Colposcopy and Cervical Pathology.

Discontinuation of Screening

For women in the HTW age group, screening should be discontinued after a hysterectomy with removal of the cervix if the patient has no prior history of CIN 2 or greater.

References

- American Society for Colposcopy and Cervical Pathology (2013). Consensus guidelines for managing abnormal cervical cancer screens & CIN/AIS. Available at https://www.asccp.org/guidelines
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- Practice Bulletin No. 168: Cervical cancer screening and prevention. (2016). *Obstet Gynecol, 128*(4), e111-e130.
- U.S. Department of Health and Human Services Panel on opportunistic infections in HIV-infected adults and adolescents. Guidelines for the prevention and treatment of opportunistic infections in HIV-infected adults and adolescents: recommendations from the Centers for Disease Control and prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. Available at: https://aidsinfo.nih.gov/guidelines/html/4/adult-and-adolescent-opportunistic-infection/0
- US Preventive Services Task Force, Curry, S. J., Krist, A. H., Owens, D. K., Barry, M. J., Caughey, A. B., Wong, J. B. (2018). Screening for cervical

cancer: US Preventive Services Task Force Recommendation Statement. *JAMA, 320*(7), 674-686.

Breast Cancer Screening

Note that the summary of cited guideline recommendations provided in this section reflect the ages of eligibility for HTW, and do not include guideline recommendations for patients outside this range.

Risk Screening and Patient Counseling

All patients must have an assessment of their risk for breast cancer, updated periodically, to include the patient's age and ethnicity, personal and family history of breast cancer, other relevant genetic predisposition to breast cancer, and any history of chest radiation (particularly before age 30). A risk calculator for identifying a patient's 5-year risk of developing breast cancer for women age 35 and older is available from the National Cancer Institute.

All patients should be counseled on breast awareness and advised to be familiar with their breasts and to report any changes (such as a mass, lump, thickening, or nipple discharge) promptly.

Screening Frequency

The following considerations* apply to women age 40 years and older who do not have a preexisting breast cancer or other high-risk breast lesion and who do not have a known underlying genetic mutation (such as a BRCA1 or 2 mutations, or other familial breast cancer syndrome) or a history of chest radiation at an early age.

Note that the age ranges included in the statements below reflect the age ranges covered by HTW and may not include the full age ranges included in the guideline statements used as reference.

- The decision for screening mammography in women age 40-44 years should be individualized:
  - While screening mammography may reduce cancer-related deaths in this population, the number of deaths prevented is less than in older populations and the number of false-positive mammography results and negative biopsies is higher.

  - Women who undergo regular screening mammography face a risk of the diagnosis and subsequent treatment of breast cancer that would not otherwise have become apparent or threatened their health during their lifetime (overtreatment).
  - Women with a first-degree relative (parent, sibling, or child) with breast cancer are at increased risk and may benefit more from screening in their 40s than average-risk women.
  - Women who place a higher value on the potential benefits of screening than on the potential harms may choose, and should be allowed, to undergo biennial screening beginning sometime during her 40s.
- Screening mammography combined with breast tomosynthesis appears to improve the rate of cancer detection and decrease call-back rates, although this practice may increase the total radiation dose.
- Young women and women with dense breasts appear to benefit from full-field digital mammography. Dense breasts limit the sensitivity of mammography and are associated with an increased risk for breast cancer.
- Automated or hand-held ultrasound can increase the detection of cancer but may increase recall rates and the frequency of benign biopsies.
- Breast magnetic resonance imaging is appropriate as an adjunct to screening mammography in certain high-risk populations. See NCCN clinical practice guideline on breast cancer screening.

More frequent or earlier screening mammography may be considered in women with increased or uncertain individual breast cancer risk and in other circumstances where the balance of potential benefits and harms of screening is felt to justify it.

*Note that the recommendations for frequency of mammography screening described above come from the U.S. Preventive Services Task Force Recommendation Statement on Screening for Breast Cancer (Sui, 2016). The National Comprehensive Cancer Network recommends annual screening mammography be offered to all asymptomatic women age 40 and older. Links to both guidelines are provided in the References section immediately below.

Follow-up and Referral for Treatment

Any patient with an abnormality identified on screening or a specific breast complaint (including, but not limited to, a mass, lump, thickening, or nipple discharge) must be evaluated as indicated in a timely manner. Providers should have procedures in place to ensure appropriate patient education and counseling,

referral for further evaluation (including additional testing and biopsy) when indicated, communication and coordination with the patient and other providers, and proper follow-up through the conclusion of the case.

For patients who require referral for services beyond those available through the contracted provider, contractors are encouraged, whenever possible, to refer to a HHSC Breast and Cervical Cancer Services contractor. Information is available at: https://hhs.texas.gov/Doing-Business-HHS/Provider-Portals/Health-Services-Providers/Womens-Health-Services/Breast-Cervical-Cancer-Services

Eligible patients in need of treatment for biopsy-proven breast cancer may apply for coverage under the Medicaid for Breast and Cervical Cancer Program. Information is available at: https://yourtexasbenefits.hhsc.texas.gov/programs/health/women/breast-and-cervical-cancer

References

- Siu, AL. Screening for breast cancer: US Preventive Services Task Force Recommendation Statement. *Ann Intern Med.* 2016;164(4):279-296. Available at http://annals.org/article.aspx?articleid=2480757.
- National Comprehensive Cancer Network. (2018). NCCN clinical practice guidelines in oncology: Breast cancer screening and diagnosis. Version 2.2018. Available at: https://www.nccn.org/professionals/physician_gls/f_guidelines.asp#breast_screening.

Additional Reading

- National Comprehensive Cancer Network. (2018). NCCN clinical practice guidelines in oncology: Breast cancer risk reduction. Version 2.2018. Available at: https://www.nccn.org/professionals/physician_gls/f_guidelines.asp#breast_risk.
- National Comprehensive Cancer Network. (2017). NCCN clinical practice guidelines in oncology: Genetic/familial high-risk assessment: Breast and ovarian. Version 1.2018. Available at: https://www.nccn.org/professionals/physician_gls/f_guidelines.asp#breast_risk

Information for Patients

- National Cancer Institute. Mammograms patient information page. Available at: http://www.cancer.gov/types/breast/mammograms-fact-sheet
- National Cancer Institute. Breast Cancer – Patient Version. Available at: http://www.cancer.gov/types/breast

Online Provider Resources

- National Cancer Institute. Breast Cancer Risk Assessment Tool. Available at: https://bcrisktool.cancer.gov/

Sexually Transmitted Disease/Infection (STD/STI) Screening and Treatment

Screening and treatment of STD/STIs must follow the current guidelines for screening and treatment from the Centers for Disease Control and Prevention (CDC). A risk assessment should be done for all clients to determine what testing is indicated and documented in the medical record as well. The following is a brief overview of STD/STI screening recommendations (for more detailed information, go to the CDC screening link above).

HIV Screening:

- Contractors must provide HIV testing, either on-site or by referral.
- If HIV testing is done, verbal or written consent, should be documented in the medical record. If testing is indicated and the client declines, this should be documented.
- All HTW clients age 15 through 44, who have not previously been screened, should be screened at least once for HIV, using a policy that provides HIV education and allows patients to opt out of screening if desired. With opt-out screening, patients are informed, prior to testing, that HIV testing will be done as part of the general consent for care and they are free to decline testing if they choose to do so; if they do not decline, the test is performed.
- Clients who engage in risky sexual practices or share injection drug paraphernalia should be tested annually.
- Clients who seek testing or treatment of STD/STIs should be tested for HIV at the same time.
- Contractors may provide negative HIV test results to patients in person, by telephone, or by the same method or manner as the results of other

diagnostic or screening tests. The provision of negative test results by telephone must follow procedures that address patient confidentiality, identification of the client, and prevention counseling.

- Contractors must always provide positive HIV test results to patients in a face-to-face encounter with an immediate opportunity for counseling and referral to community support services. Test results must be provided by staff knowledgeable about HIV prevention and HIV testing.
- Clients whose risk assessment reveals high-risk behaviors should be provided directly or referred for, more extensive risk reduction counseling by a Department of State Health Services (DSHS) HIV/STD Program trained risk reduction specialist.
- Persons with a diagnosis of HIV should be referred to a DSHS HIV/STD Program contractor for treatment and monitoring.
- To find a DSHS HIV/STD Program contractor, visit the DSHS HIV/STD website.

Chlamydia and Gonorrhea Testing:

- Annual chlamydia and gonorrhea screening should be provided for all sexually active women under age 25. If a pelvic examination will not be performed, as in asymptomatic women under 21 years of age and other women who decline a pelvic examination, screening can be performed using a nucleic acid amplification technique on a urine sample or a patient self-obtained vaginal swab.
- Testing should also be done in older asymptomatic women with increased risk and in all symptomatic women. Indications include, but are not limited to:
  - New or multiple sex partners
  - A partner who has another partner(s)
  - Exposure to an STD/STI
  - Symptoms or signs of cervicitis or an STD/STI
  - History of pelvic inflammatory disease
  - A positive test for an STD/STI in the prior 12 months
  - Sex work or drug use
- Treated patients should be retested approximately three to four months after treatment to assess evidence of reinfection.
- All women who are pregnant or attempting pregnancy should be tested.

- Routine screening of male patients for chlamydia and gonorrhea is not recommended but should be considered in settings where the prevalence of infection is high such as correctional facilities and adolescent clinics.

Herpes Simplex Virus (HSV) Screening:

- Routine screening of asymptomatic patients for genital herpes simplex virus (HSV) infection is not recommended in the general or pregnant population.
- Testing, counseling, and treatment of symptomatic patients (i.e., presence of genital lesions), as well as management of affected pregnant patients, should follow current CDC guidelines.
- The preferred tests for confirmation of the diagnosis in patients with active genital ulcers or mucocutaneous lesions are cell culture and polymerase chain reaction (PCR) assay.
- Type-specific serologic testing may be appropriate in some circumstances:
  - For women presenting for evaluation of an STD/STI (especially those who report multiple sexual partners), and women with HIV infection
  - When the diagnosis is suspected, but no lesions are present (a culture or PCR assay is not indicated if no lesions are present)
  - When the diagnosis is uncertain and virologic tests (i.e., culture and PCR) are negative in a symptomatic patient
  - For counseling patients regarding the risk of infection by a partner with known infection.

Syphilis Screening (non-pregnant women):

- Nonpregnant women who are at increased risk of syphilis infection should undergo screening for syphilis.
- Among women, those who are living with HIV have the highest risk for syphilis infection.
- Other factors associated with increased prevalence of syphilis infection are a history of incarceration or commercial sex work.
- According to 2014 surveillance data, approximately nine percent of cases of syphilis occurred in women.
- Syphilis prevalence (per 100,000 population) in the U.S. varied by race and ethnicity in 2014:
  - Black: 18.9
  - Hispanic and American Indian/Alaska Native: 7.6
  - Native Hawaiian/Pacific Islander: 6.5
  - White: 3.5

  - Asian: 2.8
- Routine screening for syphilis in a nonpregnant population that is not at increased risk of syphilis infection is not recommended because it may yield a high false-positive rate, leading to overtreatment.

Screening for other infections and more frequent screening should be considered as appropriate based on the patient's condition, risk factors, and concerns.

Patient-Delivered Partner Therapy

Patient-delivered partner therapy (PDPT) is the practice of providing therapy to the sexual partner(s) of a person being treated for chlamydia or gonorrhea without first developing a patient-clinician relationship with the partner(s). An amendment to the Texas Administrative Code, Chapter 22, Section 190.8, [Texas Secretary of State], adopted in June, 2009 by the Texas Medical Board, expressly allows PDPT. The exception created by this amendment acknowledges the serious impact of sexually transmitted diseases and the contribution of untreated partners to the reinfection of treated patients and exposure of others to infection. Providers are encouraged to implement PDPT by providing patients who are being treated for either chlamydia or gonorrhea with medications or prescriptions the partner(s) can use to be treated as well.

Providers may not receive reimbursement for providing partner treatment under this policy to persons who have not been seen as patients.

References

- American College of Obstetricians and Gynecologists. Committee Opinion No. 598: The initial reproductive health visit. *Obstet Gynecol* (2014) 123: 1143-1147. Available at: http://www.acog.org/Resources_And_Publications/Committee_Opinions/Committee_on_Adolescent_Health_Care/The_Initial_Reproductive_Health_Visit
- Branson, BM., et al. Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. *MMWR* (2006) 55(RR14): 1-17. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm
- Centers for Disease Control and Prevention. Genital herpes. Available at http://www.cdc.gov/std/Herpes/default.htm

- Centers for Disease Control and Prevention. Pregnant women, infants, and children: An opt-out approach to HIV screening. Available at: http://www.cdc.gov/hiv/group/gender/pregnantwomen/opt-out.html
- Centers for Disease Control and Prevention. Sexually transmitted diseases: Treatment. Available at: http://www.cdc.gov/std/treatment/default.htm
- Centers for Disease Control and Prevention. STD & HIV Screening Recommendations. Available at: http://www.cdc.gov/std/prevention/screeningreccs.htm
- U.S. Preventive Services Task Force. Screening for syphilis infection in non-pregnant adults and adolescents: U.S. Preventive Services Task Force recommendation statement. *JAMA* (2016) 315(21): 2321-2327. Available at:
- http://jamanetwork.com/journals/jama/fullarticle/2526645

Resources for Patients and Providers:

- Centers for Disease Control and Prevention. Expedited partner therapy website. Includes information for patients and providers on expedited partner therapy. Available at: http://www.cdc.gov/std/ept/
- Texas Dept. of State Health Services. Expedited partner therapy website. Available at: http://www.dshs.state.tx.us/hivstd/ept/default.shtm
- Texas Dept. of State Health Services. HIV-STD Program website. Information on many topics related to HIV testing and treatment, including contact information for local HIV/AIDS clinical care providers by city. Available at: http://dshs.texas.gov/hivstd/

Healthy Lifestyle Intervention

All clients should receive a health risk survey at least annually, to determine areas where lifestyle modifications might reduce the risk of future disease and improve health outcomes and quality of life.

Counseling on Healthy Lifestyle Choices

- All clients should be advised not to smoke or to use tobacco products, and to avoid exposure to second-hand smoke as much as possible. Those who use tobacco products should be advised to quit and assessed for their readiness to do so at each encounter.

- Clients should be counseled on healthy eating patterns and offered access to relevant information.
- Clients should be advised to limit their salt intake.
- Clients should be advised to engage in at least 30 minutes of physical activity or resistance training, tailored to their own health condition and risks, at least three days per week, with no more than two consecutive inactive days. More frequent and longer duration (e.g., 60 minutes/day) activity is better.
- See the following section details on why and how to achieve some of these goals.

Diet and Nutrition

There is strong evidence that nutrition plays an important role in our risk of disease. Dietary patterns that emphasize a lower percentage of total calories from fat, reduced amounts of saturated fats, and reduced sodium intake while achieving and maintaining a healthy body weight, have been shown to reduce the risk of cardiovascular disease, the most common cause of death in both men and women in the United States. No single diet has been shown to be the best, and providers should counsel clients on a variety of healthy eating patterns tailored to their particular health condition and cultural background, while preserving the pleasure of meals and eating.

Healthy Dietary Patterns

Two dietary patterns that have been shown to improve some measures of cardiovascular risk are the Dietary Approaches to Stop Hypertension (DASH) and Mediterranean (MED) diets. Both dietary patterns emphasize reduced saturated fat and red meat; and increased fiber, vegetables, fruits, fish, oils, and nuts, while allowing wide freedom of food choices to accommodate eating preferences and cultural differences among people.

The MED diet emphasizes:

- Increased servings of fruits (particularly fresh fruits), vegetables (particularly green and root vegetables), whole grains (such as whole-grain breads, rice, pasta, and cereals), and fatty fish (which are rich in omega-3 fatty acids);
- Reduced amounts of red meat (emphasizing lean meats when meat is eaten);
- Substituting lower fat or fat-free dairy products for higher fat options; and

- Using oils (such as olive or canola), nuts (such as walnuts, almonds, or hazelnuts), or margarines containing flaxseed or rapeseed oil, in place of butter and other saturated fats.

The DASH diet is:

- High in vegetables, fruits, low-fat or fat-free dairy products, whole grains, poultry, fish, legumes, and nuts;
- Low in sweets, sugar-sweetened beverages, and red meats; and
- Lower in total fat and saturated fat than a typical American diet.

Dietary counseling on healthy eating patterns, such as those described above, provided as a routine part of a client encounter, has been shown to reduce blood pressure in those with type 2 diabetes or risk factors for cardiovascular disease, including those with mild untreated hypertension. For patients with normal or modestly elevated cholesterol, regardless of gender or ethnicity, following a DASH dietary pattern can reduce low-density-lipoprotein cholesterol (LDL-cholesterol) and high-density-lipoprotein cholesterol (HDL-cholesterol). Following a DASH dietary pattern can reduce blood pressure in all people, regardless of age, gender, and ethnicity, including those with mild untreated hypertension.

Salt Intake

There is strong evidence that reducing sodium (salt) intake reduces blood pressure in people with normal blood pressure as well as those with mild to moderate hypertension, regardless of gender, ethnicity, and age. This holds true even if no other dietary changes are made. Therefore, some people who consider the dietary patterns described above too drastic a change can reduce their blood pressure just by lowering their salt intake. Those who adopt a DASH dietary pattern and reduce their salt intake can lower their blood pressure even more. All clients should receive advice to limit their salt intake and counseled on ways to do so.

Cholesterol

Despite much public attention given to cholesterol in the diet as a cause of poor health, there has been very little research on the effect of reducing dietary cholesterol on the risk of future disease; therefore, no recommendation can be made to counsel clients on dietary cholesterol intake specifically.

Physical Activity

Regular aerobic physical activity (e.g., walking, jogging, dancing, swimming, water-walking, gardening, climbing stairs, even house cleaning) and resistance training (e.g., working with light weights or elastic bands) can reduce the risk of serious disease by lowering LDL-cholesterol and blood pressure. Clients should be encouraged to engage in at least 30 minutes of an activity they enjoy, suitable to their current health status and risk, at least three times a week, with no more than two consecutive inactive days. More intensive physical activity (e.g., up to 60 minutes at a setting, more sessions per week), for those whose health status permits, offer more benefit.

Reference

- National Heart, Lung, and Blood Institute. Lifestyle interventions to reduce cardiovascular risk: Systematic Evidence Review from the Lifestyle Work Group (2013). Available at: https://www.nhlbi.nih.gov/health-topics/lifestyle-interventions-reduce-cardiovascular-risk

Information for Patients and Educators

- American Heart Association. Healthy Eating. Provides information on food choices, recipes, how to eat healthy when dining out, and how to shop for groceries with a focus on healthy eating. Available at: http://www.heart.org/HEARTORG/HealthyLiving/HealthyEating/Healthy-Eating_UCM_001188_SubHomePage.jsp
- American Heart Association. Get moving! Easy tips to get active. Provides information on physical activity and fitness. Available at: http://www.heart.org/HEARTORG/HealthyLiving/PhysicalActivity/Physical-Activity_UCM_001080_SubHomePage.jsp
- American Heart Association. Sodium and Salt. Provides information on ways to reduce dietary salt intake. Available at: http://www.heart.org/HEARTORG/HealthyLiving/HealthyEating/Nutrition/Sodium-and-Salt_UCM_303290_Article.jsp#.WThZ4-v1DRY
- Mayo Clinic. Healthy diets. Available at: http://www.mayoclinic.org/healthy-lifestyle/nutrition-and-healthy-eating/basics/healthy-diets/hlv-20049477

- Mayo Clinic. DASH diet: Healthy eating to lower your blood pressure. Available at: http://www.mayoclinic.org/healthy-lifestyle/nutrition-and-healthy-eating/in-depth/dash-diet/art-20048456
- Mayo Clinic. DASH diet recipes. Available at: http://www.mayoclinic.org/healthy-lifestyle/recipes/dash-diet-recipes/rcs-20077146
- Mayo Clinic. Mediterranean diet recipes. Available at: http://www.mayoclinic.org/healthy-lifestyle/nutrition-and-healthy-eating/in-depth/mediterranean-diet-recipes/art-20046682

Diabetes Mellitus Screening, Prevention, and Treatment

Note that the summary of cited guideline recommendations provided in this section reflect the ages of eligibility for HTW, and do not include guideline recommendations for patients outside this eligibility range.

Who should be screened for diabetes

The screening criteria below apply to nonpregnant patients only.

1. Screen adults < age 45 who are overweight or obese (BMI $\geq$ 25 kg/m^2 [BMI $\geq$ 23 kg/m^2 for Asian Americans]) with one or more risk factor. An adult BMI calculator is available from the Centers for Disease Control and Prevention (CDC).
2. Screen overweight or obese children or adolescents (age 19 or younger) with two or more additional risk factors. To determine whether the client is overweight or obese, see the CDC web page Defining Childhood Obesity and the child and teen BMI Calculator provided by the CDC.
3. If test results are normal, retest at least every three years. Consider more frequent testing in patients with risk factors.
4. Patients with prediabetes (IFG or IGT) should be retested every year.
   a. IFG and IGT refer to laboratory values that are above the normal range but do not meet the diagnostic criteria for diabetes.
   b. Persons with these results are said to have "prediabetes."
5. All women with a diagnosis of gestational diabetes in a recent pregnancy should have diabetes screening with a two-hour oral glucose tolerance test at 6-12 weeks postpartum, regardless of other risk factors.

6. All women with any history of gestational diabetes should have testing for diabetes and prediabetes at least every three years, regardless of other risk factors.

Risk Factors for diabetes

- High-risk race or ethnicity (e.g., Latino, African American, Asian American, Native American, Pacific Islander)
- Diabetes in a first-degree relative
- Physical inactivity
- Women who ever had gestational diabetes or delivered a baby weighing more than nine pounds.
- History of prediabetes: hemoglobin A1C > 5.7 percent (39 mmol/mol), impaired fasting glucose (IFG), or impaired glucose tolerance (IGT) in previous testing
- HDL cholesterol < 35 mg/dL (0.90 mmol/L) and/or serum triglyceride level > 250 mg/dL (2.82 mmol/L)
- A history of polycystic ovary syndrome
- A diagnosis of hypertension
- A history of cardiovascular disease
- Any other condition in which insulin resistance is common, such as severe obesity or acanthosis nigricans

Diagnostic Criteria

Any one or more of the following results, confirmed on repeat testing, meets the criteria for a diagnosis of diabetes (repeat testing for confirmation is not required in the presence of unequivocal clinical hyperglycemia):

1. Fasting plasma glucose (after no caloric intake for a minimum of 8 hours) > 126 mg/dL (7.0 mmol/L)
2. Oral glucose tolerance test (OGTT) with a 2-hour postprandial glucose level > 200 mg/dL (11.1. mmol/L) following a 75-g glucose load
3. Hemoglobin A1C > 6.5 percent (48 mmol/mol) (For diagnosis of type I diabetes in patients with acute hyperglycemic symptoms, blood glucose testing is preferred.)
   Random plasma glucose > 200 mg/dL (11.1. mmol/L) in the setting of a hyperglycemic crisis or classic symptoms of hyperglycemia (Confirmation by repeat testing is not required in this setting.)

The following table summarizes the diagnostic criteria for diabetes mellitus.

Test	Criteria to Diagnose Diabetes Mellitus	Comments
Fasting plasma glucose	>/= 126 mg/dL (7.0 mmol/L)	After no caloric intake for a minimum of 8 hours
Oral glucose tolerance test (with a 75-g glucose load)	2-hour glucose >/= 200 mg/dL (11.1. mmol/L)	
Hemoglobin A1C	>/= 6.5% (48 mmol/mol)	For diagnosis of type I diabetes in patients with acute hyperglycemic symptoms, blood glucose testing is preferred
Random plasma glucose	>/= 200 mg/dL (11.1. mmol/L)	If this occurs in the setting of a hyperglycemic crisis or classic symptoms of hyperglycemia, confirmation by repeat testing is not required

Table. Diagnostic criteria for diabetes. Unless stated otherwise, all initial results should be confirmed with repeat testing.

Treatment Considerations

A thorough review of the management of Type 1 and Type 2 diabetes mellitus is beyond the scope of this policy manual. The reader is referred to the references at the end of this section and relevant textbooks for a more detailed discussion.

Diabetes care should be patient-centered, team-oriented, and individualized, and should take the patient's social and cultural background and preferences into account. The foundations of diabetes care include

- Diabetes self-management education (DSME), diabetes self-management support (DSMS), medical nutrition therapy (MNT), and physical activity
- Tobacco use cessation as indicated
- Immunizations
- Psychosocial care
- Medications as needed

Evaluation of the Diabetic Patient

A comprehensive evaluation of the patient with diabetes should include a thorough medical and psychosocial history, updated as appropriate at periodic intervals and when changes occur in the patient's health.

A comprehensive physical examination should include all the following items:

- Height, weight, and BMI
- For children and adolescent patients, evaluation of growth and pubertal development
- BP measurement
- Fundoscopic examination
- Palpation of the thyroid
- Examination of the skin
- Foot examination
  - Inspection
  - Posterior tibial and dorsalis pedis pulses
  - Patellar and Achilles reflexes
  - Assessment of proprioception, monofilament sensation, and vibration

Laboratory evaluation at the time of comprehensive workup should include:

- Hemoglobin A1C if not done in the previous three months
- Annual fasting lipid profile, liver function tests, and spot urinary albumin-to-creatinine ratio
- Annual serum creatinine with estimation of glomerular filtration rate
- Annual thyroid-stimulating hormone for patients with dyslipidemia or Type 1 diabetes

Diabetes Self-Management Education (DSME) and Support (DSMS)

DSME and DSMS are essential components of diabetes care. All patients with diabetes should receive DSME aimed at developing and maintaining the knowledge and skills necessary for optimal self-care and self-management. Four critical time points for delivery of DSME and DSMS have been identified:

1. At the time of initial diagnosis of diabetes
2. Annually for the reassessment of education, nutrition, and emotional needs
3. At the time of changes in the patient's condition that influence self-management
4. Whenever a transition of care occurs

Medical Nutrition Therapy

All patients with diabetes should receive individualized medial nutrition therapy (MNT), developed in a collaborative process involving the patient and the healthcare team, preferably guided by a registered dietitian, and tailored to the patient's needs, preferences, and cultural background. MNT should promote healthy eating habits, preserve the enjoyment of food, and provide the practical tools necessary to maintain a healthy eating pattern throughout life.

Nutrition counselors and educators should become aware of, and take into account, issues that may influence or impair a particular patient's ability to understand or comply with MNT, such as food insecurity, low educational level, poor literacy (and/or poor numeracy – inability to work with numbers), and homelessness. Where needs are identified, clients should be referred to appropriate resources in the community for assistance.

For people who are overweight or obese, modest weight loss (sustained loss of 5-7 percent of body weight) may improve blood glucose control and reduce the need for medication in those with type 2 diabetes and may delay the progression to type 2 diabetes in those with prediabetes.

Physical Activity

Regular exercise has been shown to improve blood glucose control, support weight loss, reduce the risk of cardiovascular disease, and improve well-being in persons with diabetes. Furthermore, it may help to prevent or delay the development of type 2 diabetes in people who are high risk. All people with diabetes should be

advised to engage in at least 150 minutes per week of moderate-intensity physical activity, divided over at least 3 days each week, with no more than two consecutive days without exercise. If no contraindications exist, those with type 2 diabetes should engage in resistance training (e. g., working with light hand or leg weights) at least twice weekly.

Tobacco Use Cessation

All patients should have a thorough assessment of tobacco use and exposure, including the use of cigarettes, other tobacco products, and e-cigarettes, and exposure to second-hand smoke, updated at periodic intervals. Users should be assessed regularly for their readiness to quit and receive cessation counseling and information on other forms of cessation treatment.

Immunization

- Persons with diabetes should receive routine vaccinations based on age-related recommendations for the general population, including but not limited to influenza and pneumococcal vaccines.
- In addition, unvaccinated adults age 19-44 with diabetes should receive the hepatitis B vaccine.

Psychosocial Issues

Because psychosocial issues can substantially impair a person's ability to optimally self-manage diabetes and adversely affect outcomes, providers should routinely address each person's psychological and social situation, including such things as:

- Attitudes toward diabetes and expectations of treatment and outcomes;
- Quality of life, both general and diabetes-related;
- Availability of resources (financial, logistical, social, and emotional); and
- Psychiatric history.

Patients should receive periodic routine screening for psychosocial problems such as depression, diabetes-related distress, anxiety, eating disorders, and cognitive impairment. A team approach to care is encouraged, with consideration of referral to a mental health specialist as indicated.

Glucose Monitoring and Glycemic Targets

Self-monitoring of blood glucose (SMBG) is appropriate for some patients, especially those on intensive insulin therapy (multiple-dose or insulin pump) and may be useful in patients on less intensive insulin therapy and non-insulin therapies, to help guide treatment. For patients with type 2 diabetes on non-insulin regimens, SMBG may not be clinically beneficial or cost-effective, and the decision should be individualized based on whether the information obtained will influence patient management. A detailed review of SMBG and its use in management of diabetes is out of scope for this clinical policy manual. Refer to the Standards of medical care in diabetes by the American Diabetes Association (see Reference section below) for a more detailed discussion.

All patients with diabetes should undergo periodic testing of hemoglobin A1C according to the following schedule:

- At least twice a year in patients who are meeting their treatment goals
- Quarterly in patients whose therapy has recently changed or who have not been meeting their glycemic goals
- More frequent testing should be considered based on individual criteria.
- Targets for hemoglobin A1C should be individualized according to the patient's circumstances:
- For most nonpregnant adults, a target value < 7 percent (53 mmol/mol) is reasonable.
- A more stringent goal (< 6.5 percent [48 mmol/mol]) may be reasonable for some patients (e.g., diabetes of short duration, type 2 diabetes controlled by lifestyle or metformin alone, absence of significant cardiovascular disease, or long-life expectancy) if it can be achieved without substantial hypoglycemia or other adverse effects.
- A less stringent goal (< 8 percent [64 mmol/mol]) may be appropriate for patients with a history of severe hypoglycemia, advanced micro- or macrovascular complications, limited life expectancy, extensive comorbid conditions, or long-standing diabetes where the more stringent target has proven difficult to achieve despite optimal management efforts.

Hypoglycemia

A thorough review of the treatment and prevention of hypoglycemia in diabetic patients is out of scope for this clinical policy manual. Refer to the Standards of

medical care in diabetes by the American Diabetes Association (see Reference section below) for a more detailed discussion.

All patients should be evaluated for their risk of hypoglycemia, and questioned for any history of hypoglycemic episodes, severe hypoglycemia, and hypoglycemia unawareness. Patients with increased risk or a positive history of hypoglycemia may benefit from SMBG to guide treatment to reduce hypoglycemia risk. Patients should be counseled on situations of increased risk (e.g., fasting for laboratory tests or procedures, during or after intense exercise, while sleeping, when unable to eat normally due to illness, or with changes in diet as with calorie restriction for weight loss). They should be advised on measures to take, such as ingesting glucose-containing foods, when they experience or suspect hypoglycemia.

Consideration should be given to referral of patients at increased risk of hypoglycemia to a diabetes specialist for their care.

Management of Obesity in Prediabetes and Type 2 Diabetes

There is clear evidence that management of obesity can delay the progression to type 2 diabetes in people with prediabetes and can be beneficial in persons with type 2 diabetes.

Sustained weight loss can be achieved with dietary calorie restriction and regular moderate-intensity physical activity and requires the commitment of the patient and the support and encouragement of the healthcare team. Patient education is an essential element of a program aimed at bringing about the lifestyle changes necessary to achieve and maintain a healthier body weight.

Following is a list of recommended practices for providers who care for patients with type 2 diabetes to promote weight management:

- Calculate BMI at each patient encounter and document in the medical record. An Adult BMI calculator and a BMI calculator for children and teens are available from the Centers for Disease Control and Prevention.
- Determine if the person is overweight or obese (these are values for non-Asian Americans):
  - BMI < 18.5 kg/m^2: Underweight
  - BMI 18.5 – 24.9 kg/m^2: Normal
  - BMI 25.0 – 29.9 kg/m^2: Overweight
  - BMI $\geq$ 30.0 kg/m^2: Obese

- Use the following criteria to assess overweight and obesity for Asian Americans:
  - BMI < 23 kg/m2: Normal
  - BMI 23.0 – 27.4 kg/m2: Overweight
  - BMI 27.5 – 37.4 kg/m2: Obese
  - BMI > 37.5 kg/m2: Extremely Obese
- Prescribe interventions aimed at achieving a 5 percent weight reduction in patients who are overweight or obese; and evaluate and document the person's readiness to lose weight.
- During the early phase of a weight-loss program, weight loss interventions (e.g., group education sessions, interaction with provider, etc.) should occur at least 16 times over a six-month period and focus on diet, physical activity, and behavioral strategies designed to achieve a daily energy deficit of 500-750 kilocalories. This high frequency of interventions in the early phase of the program is important for providing patient support for early compliance and program success. Diets should provide approximately 1,200-1,500 kcal/day for women or 1,500-1,800 kcal/day for men.
- If weight loss is achieved over the short term, prescribe a longer-term weight maintenance program that includes continuation of a reduced calorie diet, at least monthly contact with the provider, monitoring of body weight at least weekly, and 200-300 minutes of physical activity every week.
- Diets that differ in the distribution of carbohydrate, fat, and protein are equally effective in achieving weight loss as long as the total calorie consumption is the same.
- Frequent contact between the patient and the care team is important for patient engagement and the success of a sustained weight loss program. Providers are encouraged to develop creative local patient education and engagement programs that make use of group sessions, resources available in the community, and patient and educator resources available from organizations like the American Diabetes Association and the National Diabetes Education Initiative (see links below in the "Resources for patients and educators" section). Frequent interventions (two to three times per week) are particularly helpful in the beginning, while the patient is learning new lifestyle habits and is receptive to change. As initial success with weight loss is achieved, less frequent intervention (monthly) is needed to reinforce healthy habits and learning.

Medical Therapy

A thorough treatment of the pharmaceutical management of type 1 and type 2 diabetes is out of scope for this manual. Refer to the Standards of medical care in diabetes by the American Diabetes Association and relevant textbooks for further information. For patients with multiple comorbid conditions, those who present with marked symptomatology or markedly elevated laboratory values, those who fail initial therapy, and those whose diabetes proves difficult to manage, consideration may be given to referring the patient to a specialist in the treatment of diabetes.

Type 1 Diabetes

Most persons with type 1 diabetes will require multiple-dose insulin injections or continuous subcutaneous insulin infusion. Refer to the Standards of medical care in diabetes by the American Diabetes Association and relevant textbooks for further information. Consideration may be given to referring the patient to a specialist in the treatment of diabetes.

Type 2 Diabetes

- For most people with type 2 diabetes who require pharmaceutical therapy, metformin is the preferred initial agent if no contraindications exist.
- Consider insulin therapy (with or without other agents) for patients who are very symptomatic and/or demonstrate markedly elevated glucose or hemoglobin A1c levels at the time of diagnosis.
- For patients who do not achieve or maintain target hemoglobin A1c values after three months of noninsulin single-drug therapy at the maximum tolerated dose, add a second oral agent or basal insulin.
- If glycemic goals cannot be achieved on oral agents, insulin therapy should not be delayed.
- Apply a patient-centered approach to selection of pharmaceutical therapy, taking into consideration such things as efficacy, side effects, cost, and patient considerations such as weight, comorbidities, risk of hypoglycemia, and personal preferences.

For a more detailed discussion of pharmaceutical therapy in patients with type 2 diabetes, refer to the section "Approaches to Glycemic Treatment" in the Standards of medical care in diabetes by the American Diabetes Association and relevant textbooks.

References

- American College of Obstetricians and Gynecologists (2013). Practice Bulletin No. 137: Gestational diabetes mellitus. *Obstet Gynecol*. 122 406-416.
- American Diabetes Association. Standards of medical care in diabetes – 2018. *Diabetes Care* (2018); 41(Suppl. 1). Available at: http://care.diabetesjournals.org/content/41/Supplement_1

Resources for patients and educators

- American Diabetes Association home page: http://www.diabetes.org
- American Diabetes Association DiabetesPro website (information for providers of care): http://professional.diabetes.org
- American Diabetes Association Diabetes Educators (information and resources for both patients and educators): http://professional.diabetes.org/diabetes-education
- Centers for Disease Control and Prevention. Adult BMI calculator. Available at: http://www.cdc.gov/healthyweight/assessing/bmi/adult_bmi/english_bmi_calculator/bmi_calculator.html
- Centers for Disease Control and Prevention. BMI calculator for child and teen. Available at: http://nccd.cdc.gov/dnpabmi/Calculator.aspx
- Centers for Disease Control and Prevention. Defining childhood obesity web page (provides definition of overweight and obesity in children and adolescents age 2 to 19, and link to BMI calculator for children and teens). Available at: http://www.cdc.gov/obesity/childhood/defining.html
- National Diabetes Education Initiative (patient education handouts and links to professional resources): https://www.niddk.nih.gov/health-information/communication-programs/ndep
- National Institute of Diabetes and Digestive Diseases. National Diabetes Education Program (resources for patients and educators). Available at: http://www.niddk.nih.gov/health-information/health-communication-programs/ndep/pages/index.aspx
- National Heart, Lung, and Blood Institute Aim for a Healthy Weight website: https://www.nhlbi.nih.gov/health/educational/lose_wt

Hypertension Screening and Treatment

This section is intended to serve as a guide for the diagnosis and management of hypertension by primary care providers. A detailed treatment of the management of hypertension, particularly in patients with multiple coexisting health conditions and those whose blood pressure is difficult to control, is out of scope for this clinical policy manual. Refer to the References and Resources for Providers sections below as well as relevant textbooks for a more thorough discussion of the topic. Providers are encouraged to seek consultation from a specialist in the relevant area of medicine for management of complex patients and those whose blood pressure is difficult to control.

Note that the summary of cited guideline recommendations provided in this section reflect the ages of eligibility for HTW and do not reflect guideline recommendations for patients outside this eligibility range.

Classification of BP and Diagnosis of Hypertension

In the United States, high blood pressure (BP) is the second leading cause of preventable death after cigarette smoking and is the most important modifiable risk factor for death due to cardiovascular disease. Because hypertension is generally asymptomatic, it is important that all persons be screened at least annually for elevated BP.

The following table provides guidance on diagnosis and management of hypertension in adults. Recent guidelines emphasize greater reliance on home BP monitoring to aid in the diagnosis of hypertension when clinic readings are high normal, borderline high, or elevated. It is generally agreed that clinic BP measurements are often higher than home BP measurements, particularly in the higher ranges of BP.

BP Category (mm Hg)	Management
Normal BP <120/80	Optimize healthy lifestyle habits, reevaluate BP in one year.

Elevated BP **120-129/<80**	Offer nonpharmacologic therapy (healthy lifestyle intervention), reevaluate BP in three to six months.
Stage 1 Hypertension **130-139/80-89**	Assess 10-year cardiovascular disease risk. • If <10 percent, offer nonpharmacologic therapy and reevaluate BP in three to six months. • If >/=10 percent, offer nonpharmacologic therapy and antihypertensive medication; reevaluate BP in 1 month. o If BP at target goal, reevaluate in three to six months. o If BP above target goal, ensure optimal adherence to therapy and consider more intensive therapy.
Stage 2 Hypertension **>/=140/90**	Offer nonpharmacologic therapy and antihypertensive medication; reevaluate BP in one month. • If BP at target goal, reevaluate in three to six months. • If BP above target goal, ensure optimal adherence to therapy and consider more intensive therapy.

Measurement of Blood Pressure:

- For diagnosis and treatment of hypertension, BP readings should be based on the average of accurate measurements taken on two or more occasions using proper technique.
- Ambulatory or home BP monitoring should be performed to confirm the diagnosis of hypertension and to titrate antihypertensive medications.
- Adults not being treated for hypertension who have office BP readings of 130/80 to 160/100 mm Hg should be screened for white coat hypertension (WCH, high BP in the clinic but normal BP outside the clinic) using ambulatory or home BP monitoring.
- Periodically monitor adults with WCH using ambulatory or home BP monitoring to assess for development of sustained hypertension.
- Adults not being treated for hypertension who have office BP readings of 120/75 to 129/79 mm Hg consistently should be screened for masked

hypertension (normal BP in the clinic but high BP outside the clinic) using ambulatory or home BP monitoring.

- Adults being treated for hypertension whose clinic BP measurements are above treatment goals, but whose home BP measurements suggest WCH, should undergo ambulatory BP monitoring to determine if the BP is actually elevated.
- For adults on multiple antihypertensive medications and clinic BP readings </= 10 mm Hg above treatment goal, screen for WCH using ambulatory or home BP monitoring.
- Adults on antihypertensive medication with clinic BP at target level, who have evidence of target organ damage or increased overall cardiovascular disease risk, should undergo home BP monitoring to screen for masked uncontrolled hypertension.

Instructions for Home BP Monitoring:

- Patients should receive instruction for home BP monitoring, including interpretation of results, under medical supervision.
- An automated validated device should be used, preferably with the ability to store readings in memory.
- Correct cuff size should be verified, and the patient should be instructed to measure BP in the arm with the higher reading if a significant difference is observed between arms.
- Instruct the patient to rest quietly for at least five minutes, and avoid exercise, caffeine, and smoking for at least 30 minutes before taking BP.
- Instruct the patient to sit upright in a straight-backed chair with feet flat on the floor, legs uncrossed, and the arm supported on a flat surface with the upper arm at heart level.
- The bottom of the cuff should sit directly above the antecubital fossa.
- Two readings, taken one minute apart, should be done twice daily, in the morning before taking medications, and in the evening before eating supper. Measurements should be done daily, for one week before a clinic visit, and for one week beginning two weeks after any change in treatment regimen.
- Monitors with stored memory should be brought to all clinic appointments.
- Clinical decision making should be based on the average of readings taken on two or more occasions.

Nonpharmacologic Intervention:

All patients, regardless of BP category or treatment should receive instruction in healthy lifestyle habits, with regular reinforcement of teaching. For those who are unable to maintain BP in the normal range despite such nonpharmacologic intervention, BP-lowering medications should be considered.

- Weight loss should be advised for adults who are overweight or obese.
- Persons with elevated BP or hypertension should adopt a heart-healthy diet (e.g., DASH diet) to reduce BP.
- Sodium intake should be reduced.
- Potassium intake should be increased, preferably by dietary modification.
- Physical activity should be increased using a structured exercise program.
- Alcohol intake should be avoided or moderated (</= 1 standard drink daily for women, </= 2 standard drinks daily for men).

Thresholds for Initiating BP-lowering Medication:

While treatment based on BP alone is cost-effective, treatment based on cardiovascular disease risk, which incorporates both BP and other risk factors, is more efficient and cost-effective. Therefore, the patient's 10-year arteriosclerotic cardiovascular disease (ACSVD) risk should be calculated using the cardiovascular disease risk estimator, developed by the American College of Cardiology and American Heart Association, prior to initiating therapy and periodically to assess evolving risk estimates. The 10-year ASCVD risk is defined as the estimated risk of a first nonfatal myocardial infarction, fatal or nonfatal stroke, or death due to coronary heart disease within 10 years. This calculator incorporates multiple risk factors as well as various types of therapy, allowing providers to evaluate both existing risk and what effect certain changes in therapy might have on risk estimates.

- Persons with stage 1 hypertension (i.e., BP 130-139/80-89) should initiate BP-lowering medication if the 10-year cardiovascular disease risk is 10 percent or greater.
- All persons with stage 2 hypertension (i.e., BP >/= 140/90) should receive medication therapy.
- Patients with diabetes mellitus or chronic kidney disease should initiate BP-lowering medication for systolic BP >/= 130 or diastolic BP >/= 80, with a target goal of BP < 130/80.

BP Targets for Hypertension Treatment:

Treat adults with confirmed hypertension with a goal of systolic BP < 130 mm Hg and diastolic BP < 80 mm Hg.

Choice of BP-lowering Medication:

- First-line medications for lowering BP include the following broad classes of drugs:
  - Thiazide diuretics
  - Calcium channel blockers
  - Angiotensin modulators (angiotensin-converting enzyme inhibitors and angiotensin-receptor blockers)
- In the majority of adults in the U.S., thiazide diuretics and calcium-channel blockers are preferred as first-line therapy due to their efficacy.
- In all settings, response to therapy should be monitored regularly as described in the table above.
- In patients with stage 2 hypertension, initiate antihypertensive therapy with two first-line medications from different classes (i.e., different mechanisms of action).
- In patients with stage 1 hypertension who are candidates for BP-lowering medication as described in the table above, initiate therapy with a single first-line medication.
- If first-line therapy is not well tolerated, consider changing to a drug from a different class.
- If BP targets are not met with first-line treatment as described (i.e., monotherapy for stage 1 hypertension, two-drug therapy for stage 2 hypertension), reinforce the importance of adherence to therapy and consider adding another medication to the regimen.

References

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ACC/AHA/AAPA/ABC/ACPM/AGS/APha/ASH/ASPC/NMA/PCNA Guideline for the prevention, detection, evaluation, and management of high blood pressure in adults. *Hypertension, 71*(6), e13-e115. Available at: http://hyper.ahajournals.org/content/71/6/e13.long

- Whelton, P. K., Carey, R. M., Aronow, W. S., Casey, D. E., Collins, K. J., Himmelfarb, C. D., Wright, J. T. (2017). 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APha/ASH/ASPC/NMA/PCNA Guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: Executive Summary: A report of the American College of Cardiology/American Heart Association task force on clinical practice guidelines. *J Am Coll Cardiol, 71*(19), 2199-2269. Available at: https://www.sciencedirect.com/science/article/pii/S073510971741518X?via%3Dihub

Resources for Patients and Educators

- American Heart Association. High blood pressure. Provides information on the meaning and importance of high blood pressure, risks for and prevention of high blood pressure, blood pressure monitoring, and treatment of high blood pressure. Available at: http://www.heart.org/HEARTORG/Conditions/HighBloodPressure/High-Blood-Pressure_UCM_002020_SubHomePage.jsp
- National Heart, Lung, and Blood Institute. Description of high blood pressure. Provides a plain-language discussion of the prevention, diagnosis, and treatment of high blood pressure. Available at: http://www.nhlbi.nih.gov/health/health-topics/topics/hbp

Resources for Providers

- American Society of Hypertension. Hypertension Guidelines website: http://www.ash-us.org/About-Hypertension/Hypertension-Guidelines.aspx

High Cholesterol Screening and Treatment

The summary of cited guideline recommendations provided in this section address only women and reflect the ages of eligibility for HTW, and do not include guideline recommendations for men or for women outside this eligibility range.

The diagnosis and treatment of elevated blood cholesterol is a complex subject and a complete discussion is beyond the scope of this clinical policy manual. For more

information, providers are referred to the reference section below and relevant textbooks.

Rationale for cholesterol screening

Evidence shows that a healthy lifestyle (following a heart healthy diet, maintaining a healthy weight, regular exercise, and avoidance of tobacco products) reduces the risk of cardiovascular disease. In certain persons with specific risk factors, cholesterol-lowering medications (i.e., statins) can further reduce the risk of an adverse health event. Measurement of blood cholesterol is a component of the individual risk assessment in some patients.

Who should be screened for high cholesterol

- Women age 20 and older with increased risk for coronary heart disease (CHD)
- No recommendation is made regarding routine screening in women age 20 or older without increased risk of CHD

Risk Factors

Increased risk of CHD is defined by the presence of any one of the risk factors below. Greater risk results from the presence of multiple risk factors.

- Diabetes
- Personal history of previous CHD or non-coronary atherosclerosis
- Family history of cardiovascular disease in men before age 50 and in women before age 60
- Tobacco Use
- Hypertension
- Obesity (body mass index ≥ 30 kg/m2)

Screening Frequency

The optimal interval for screening is uncertain. Reasonable options include every five years, shorter intervals for people who have lipid levels close to those warranting therapy, and longer intervals for those not at increased risk who have had repeatedly normal lipid levels.

Screening Method

The preferred screening test for elevated cholesterol is the serum lipid panel (total cholesterol, high-density lipoprotein [HDL] cholesterol, and low-density lipoprotein [LDL] cholesterol) in the fasting or non-fasting state. If non-fasting results are used, only the total cholesterol and HDL-cholesterol are reliable. Abnormal screening results should be confirmed by a repeat sample on a separate occasion, and the average of both results should be used for risk assessment.

Evaluation of Screening Results

Results of the lipid profile should be interpreted in the context of the patient's risk factors and 10-year estimated risk of atherosclerotic cardiovascular disease (ASCVD; defined as acute coronary syndrome, myocardial infarction, stable or unstable angina, stroke, transient ischemic attack, coronary or other arterial revascularization procedure, or atherosclerotic peripheral arterial disease). A risk calculator for 10-year ASCVD risk is available from the American College of Cardiology and American Heart Association.

Studies have shown a benefit of statin therapy in patients with the following risk profiles:

- All patients with clinical ASCVD, regardless of lipid profile results
- Any patient with LDL-cholesterol > 190 mg/dL
- Patients 40-75 years of age with diabetes and LDL-cholesterol > 70-189 mg/dL and no clinical ASCVD
- Patients 40-75 years of age with diabetes and LDL-cholesterol 70-189 mg/dL and no clinical ASCVD
- Patients of any age without diabetes or clinical ASCVD, with LDL-cholesterol 70-189 mg/dL and 10-year ASCVD risk > 7.5 percent

Treatment Considerations

Consider statin therapy for patients whose risk profile and screening results suggest a possible benefit as described above. See the References section below for links to guidelines for treatment of cholesterol to reduce cardiovascular risk.

References

- Stone NJ, et al. 2013 ACC/AHA Guidelines on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults. *Circulation* (2014). 129(25 Suppl 2): S1-S45. Available at:

https://circ.ahajournals.org/content/early/2013/11/11/01.cir.0000437738.63853.7a

- National Heart, Lung, and Blood Institute. Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Cholesterol in Adults (Adult Treatment Panel III). NIH Publication No. 01-3670, May 2001. Available at: http://www.nhlbi.nih.gov/files/docs/guidelines/atp3xsum.pdf
- U.S. Preventive Services Task Force. The Guide to Clinical Preventive Services, "Lipid Disorders in Adults" (2014). Page 45. Available at: http://www.ahrq.gov/sites/default/files/publications/files/cpsguide.pdf

Further Reading

- Pursnani A, et al. Guideline-based statin eligibility, coronary artery calcification, and cardiovascular events. *JAMA* (2015) 314:134-141. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4754085/

Resources for Providers

- ASCVD Risk Estimator from the American College of Cardiology. Provides an estimate of the 10-year risk of developing ASCVD. Available at: http://tools.acc.org/ASCVD-Risk-Estimator/

Postpartum Depression Screening and Treatment

Prevalence and Risk Factors for Postpartum Depression

As many as 80 percent of new mothers experience a brief episode of the "baby blues" which may last up to about 2 weeks. Approximately 5 to 25 percent of new mothers will experience postpartum depression that warrants intervention. It typically begins in the first four to six weeks after birth of the infant but may develop any time in the first year. Risk factors for postpartum depression include all the following:

- Lack of social support
- Symptoms of depression (especially in the third trimester) or anxiety during the pregnancy
- Prior psychiatric illness or poor mental health, especially prior postpartum depression
- Family history of depression, anxiety, or bipolar disorder
- Low socio-economic status or low educational level

- Poor income or unemployment
- Poor relationship with the partner or father of the baby
- A negative attitude toward the pregnancy
- A recent stressful life event or perceived stress
- Intention to return to work
- A history of bothersome premenstrual syndrome
- A history of physical, sexual, or psychological abuse; domestic violence
- Stress related to child care issues
- Medical illness or prematurity in the infant
- A temperamentally difficult infant
- Immigrant from another country

Common signs and symptoms of postpartum depression include the following (some or none of these symptoms may be apparent):

- Difficulty sleeping even when the baby is sleeping
- Tearfulness, prone to crying
- Excessive worrying about the baby
- Excessive anxiety
- Feelings of guilt, such as the feeling that she is not a good mother
- Flat affect
- Poor appetite

Screening for Postpartum Depression

Because postpartum depression can be a serious, and sometimes life-threatening condition, all new mothers must have screening for postpartum depression at the postpartum visit. For those who screen negative, repeat screening should be considered at a later visit or when the mother takes her baby in for a checkup.

A standardized self-administered screening tool with review and follow-up questions in a face-to-face interview with the provider will ensure consistency and efficiency in the screening process. The following postpartum depression screening tools are available on-line, and have been validated for use in postpartum patients:

- Edinburgh Postnatal Depression Scale (EPDS; Cox, Holden, & Sagovsky, 1987)
- Patient Health Questionnaire-9 (PHQ-9; Spitzer, Kroenke, & Williams, 1999)
- Postpartum Depression Screening Scale (PDSS; Beck & Gable, 2001)

To ensure that all patients are screened without undue interruption of clinic workflow, a convenient approach to screening is the following:

- Give each postpartum patient a screening tool to complete while she waits for her visit with the provider.
- Score the tool and assess whether the screen is positive or negative:
  - EPDS: A score of 10 or more suggests depressive symptoms, a score of 13 or more indicates a high likelihood of major depression; a score of one or more on question #10 is an automatic positive screen because it indicates possible suicidal ideation and should be addressed appropriately.
  - PHQ-9: A score of 10 or more indicates a high risk of having or developing depression; a score of two or more on question #9 is an automatic positive screen because it indicates possible suicidal ideation and should be addressed appropriately.
  - PDSS Full form: A score of 60 or more suggests depressive symptoms, a score of 81 or more indicates a high likelihood of major depression; a score of six or more on the SUI (suicidal thoughts) subscale is an automatic positive screen because it indicates possible suicidal ideation and should be addressed appropriately.
  - PDSS Short form: A score of 14 or more indicates a high risk of major depression; a score of two or more on question #7 is an automatic positive screen because it indicates possible suicidal ideation and should be addressed appropriately.
- The provider should review the screen and discuss it with the woman and ask follow-up questions to evaluate her risk of postpartum depression.

Screening for Suicide Risk

Any patient with a positive screen based on responses to questions related to suicide risk, and any patient who expresses suicidal thoughts or ideation must be evaluated immediately for suicide risk. If the patient is felt to be acutely at risk of suicide, she must be referred for emergent evaluation and/or hospitalization as indicated.

Nonpharmacologic Treatment

Milder degrees of postpartum depression may respond well to cognitive behavioral interventions (e.g., stress management, problem solving, goal setting), provided in individual or group settings. The provider might work with the patient to develop a Postpartum Depression Action Plan and see her again in a week to assess response

to the intervention. Response can be assessed by repeating the screening tool to see if the score improves over time. If no improvement is seen, or if symptoms worsen, consideration should be given to initiating pharmaceutical therapy.

Pharmacologic Treatment

For patients with more severe symptoms and those who do not respond to nonpharmacologic therapy, selective serotonin reuptake inhibitors are commonly used to treat postpartum depression. There is no evidence that one agent is superior to any other. If the patient has taken an antidepressant in the past with good result, that agent would be a logical choice to initiate therapy.

It is generally prudent to start with a low dose and increase as needed, since the side effects of antidepressants can be a barrier to compliance, and because the lowest effective dose is preferred in the breastfeeding mother. The response to treatment can be assessed by repeating the screening tool used to diagnose postpartum depression. When remission of symptoms is achieved, treatment is generally continued for a period of time (e.g., six to nine months) and then discontinued. To minimize the side effects of suddenly discontinuing therapy, the dose can be tapered over a period of two weeks.

Referral for Additional Treatment

Patients in need of more intensive treatment for postpartum depression should be referred to a provider of behavioral health services. Providers must have arrangements in place for appropriate referral of patients to behavioral health providers in their area. For information on local behavioral health care providers, refer to the website of the Office of Mental Health Coordination of the Texas Health and Human Services Commission, or call 2-1-1.

Coding for Postpartum Depression Services

The following Current Procedural Terminology (CPT) codes are covered under the HTW program:

99201	99202	99203	99204	99205
99211	99212	99213	99214	99215

99201	99202	99203	99204	99205
90791	90792			

The Texas Clinician's Postpartum Depression Toolkit

The Texas Clinician's Postpartum Depression Toolkit, a resource for screening, diagnosis, and treatment of postpartum depression published by HHSC is available at: https://hhs.texas.gov/sites/default/files/documents/doing-business-with-hhs/providers/health/women/tx-clinicians-ppd-toolkit.pdf

References

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- Norhayati MN, et al. Magnitude and risk factors for postpartum symptoms: A literature review. *J Affect Disord* (2015). 175: 34-52.
- O'Connor E, et al. Primary care screening for and treatment of depression in pregnant and postpartum women: Evidence report and systematic review for the US Preventive Services Task Force. *JAMA* (2016). 315: 388-406.

Resources for Patients and Providers

- American Academy of Family Physicians. Postpartum Depression web page. Information for patients and providers on postpartum depression. Available at: http://familydoctor.org/familydoctor/en/diseases-conditions/postpartum-depression.html
- American Academy of Family Physicians. Postpartum Depression Action Plan. Available at: http://familydoctor.org/familydoctor/en/diseases-conditions/postpartum-depression/treatment/postpartum-depression-action-plan.html

- American Psychological Association. Postpartum Depression web page. Includes patient education brochures in English, Spanish, French, and Chinese as well as links to resources on postpartum depression for new mothers and new fathers. Available at: http://www.apa.org/pi/women/resources/reports/postpartum-dep.aspx
- Office of Mental Health Coordination website, Texas Health and Human Services Commission. Provides links to information for providers and patients in Texas on a variety of behavioral health topics, and a link to the Substance Abuse and Mental Health Services Administration (SAMHSA) behavioral health treatment services locator. Available at: http://mentalhealthtx.org/
- STEP-PPD Support and training to enhance primary care for postpartum depression website. Provides links to resources, including postpartum depression screening tools, online training, case studies, classroom materials, "Clinician's Pocket Guide," and other materials. Available at: https://step-ppd.com/
- Texas Health and Human Services Commission. The Texas Clinician's Postpartum Depression Toolkit. Contains a review of the diagnosis and treatment of postpartum depression for the primary care provider, including a section on covered services, coding, and billing for services provided under Texas state healthcare programs. Available at: https://www.healthytexaswomen.org/provider-resources#healthy-texas-women

CHAPTER 3: REIMBURSMENT

Provider Reimbursement Criteria

To be reimbursed for HTW fee-for-service, the following eligibility requirements must be met:

- Must be a Medicaid (Title XIX) provider in accordance with 1 TAC Chapter 352.
- Must have completed the HTW certification process through the TMHP portal attesting that they do not perform or promote elective abortions and are not affiliated with an entity that performs or promotes elective abortions.

Providers can complete the certification in one of the following ways:

- Existing Medicaid providers can complete the certification process through their TMHP portal account.
- Providers that are not already enrolled in Texas Medicaid can complete the HTW certification process as part of the provider enrollment process or as part of the paper Texas Medicaid Provider Enrollment Application.
- Annual recertification is required for all HTW providers.

Per Texas Administrative Code (TAC), Title 1, Part 15, Chapter 382, Subchapter A, Rule §382.5, providers must not perform or promote elective abortions outside the scope of HTW and must not be an affiliate of an entity that performs or promotes elective abortions. In offering or performing an HTW service, the respondent must not promote elective abortion within the scope of HTW and must maintain physical and financial separation between its HTW activities and any elective abortion-performing or abortion-promoting activity, as evidenced by the following:

- Physical separation of HTW services from any elective abortion activities, no matter what entity is responsible for the activities
- A governing board or other body that controls the HTW health care provider has no board members who are also members of the governing board of an entity that performs or promotes elective abortions
- Accounting records that confirm that none of the funds used to pay for HTW services directly or indirectly support the performance or promotion of elective abortions by an affiliate

- Display of signs and other media that identify HTW and the absence of signs or materials promoting elective abortion in the provider's location or in the provider's public electronic communications
- Does not use, display, or operate under a brand name, trademark, service mark, or registered identification mark of an organization that performs or promotes elective abortions.

The term "promote" used here means advancing, furthering, advocating, or popularizing elective abortion by, for example:

- Taking affirmative action to secure elective abortion services for an HTW client (such as making an appointment, obtaining consent for the elective abortion, arranging for transportation, negotiating a reduction in an elective abortion provider fee, or arranging or scheduling an elective abortion procedure); however, the term does not include providing upon the patient's request neutral, factual information and nondirective counseling, including the name, address, telephone number, and other relevant information about a provider
- Furnishing or displaying to an HTW client information that publicizes or advertises an elective abortion service or provider
- Using, displaying, or operating under a brand name, trademark, service mark, or registered identification mark of an organization that performs or promotes elective abortions.

When enrolling as a Title XIX provider, Clinical Laboratory Improvement Amendments (CLIA) information must be provided. For public health agencies that provide limited numbers of tests, one CLIA certificate is all that is required for all clinics. Note: Based on the type of CLIA certificate a provider has, certain procedure codes may or may not be reimbursed. Please visit the Clinical Laboratory Improvement Amendments (CLIA) website for more information.

Failure to comply with these requirements will result in contract termination.

Provider Identifiers (TPI)

When a contractor's Medicaid application is approved, TMHP assigns the contractor a nine-digit Texas Provider Identifier (TPI). **Contractors must have a unique TPI for each clinical service site.**

Contractors must submit claims to TMHP using the billing TPI where clinical services are rendered. Contractors must not provide women's health and family planning services at one clinic site and bill those services to TMHP using the TPI of a different clinic site. If an additional TPI clinic site is required, providers must contact TMHP and complete the enrollment process.

The TPI is used in conjunction with a National Provider Identifier (NPI) to identify the provider for claims processing. An NPI is a 10-digit number assigned randomly by the National Plan and Provider Numeration System (NPPES). Contractors may apply for a NPI at the NPPES website.

When a provider obtains their NPI they are required to attest to NPI data for each of their current TPI. For more information on NPI and the attestation process please visit the TMHP website.

Texas Medicaid Provider & Procedures Manual

The Texas Medicaid Provider Procedures Manual (TMPPM) includes information related to HTW fee-for-service program claims submission. In addition, Medicaid bulletins and R&S banner messages provide up-to-date claims filing and payment information. The R&S banner messages, and the TMPPM are all available on the TMHP website.

Retroactive Eligibility

Title XIX Retroactive Eligibility

Retroactive eligibility occurs when a client has applied for Medicaid coverage but has not yet been assigned a Medicaid client number at the time of service. Clients who are eligible for Title XIX (Medicaid) medical assistance receive three months prior eligibility to cover any medical expenses incurred during that period.

CHAPTER 4: DATA COLLECTION AND REPORTING

Required Reporting

REQUIRED REPORTS

Financial Reporting

VOUCHER AND REPORT SUBMISSION – Cost Reimbursement

PROGRAM INFORMATION:
Program Name: HHSC Healthy Texas Women
Contract Type: Cost Reimbursement
Contract Term: September 1 thru August 31

VOUCHER

Voucher Name: HHSC State Purchase Voucher.

Submission Date: By the last business day of the following month. Final voucher due within 45 days after end of the contract term.

Submit Copy to:

Name of Area	Original Signature Required Yes	No	Accepted Method of Submission	# Copies
Women's Health & Education Services Mailbox				
Email box designated by program		X	Email (preferred), or Fax	1

Instructions: Attach B-13H to HHSC State Purchase Voucher (Form 4116).

NOTE: Vouchers must be submitted each month even if there are zero expenditures. Vouchers must still be submitted each month for actual expenditures of the program even if the contract limit has been reached.

VOUCHER SUPPORTING DOCUMENT

Report Name: Supporting Schedule (Form B-13) in Excel format for Healthy Texas Women HHSC State Purchase Voucher.

Submission Date: By the last business day of the following month. Final B-13 due within 45 days after end of the contract term.

Submit Copy to:

Name of Area	Original Signature Required Yes	Original Signature Required No	Accepted Method of Submission	# Copies
Women's Health & Education Services Mailbox Email box designated by program		X	Email (preferred), or Fax	1

Instructions: Attach B-13 to HHSC State Purchase Voucher.

FINANCIAL STATUS REPORT

Report Name: Financial Status Report (Form 269A)

Submission Date: Reports are due as follows:
Quarter 1: September – November;
Quarter 2: December – February;
Quarter 3: March – May;
Quarter 4: June – August.

Submit 30 days after the end of each quarter. The final quarterly FSR is due 45 days after the end of the contract term. The final quarter report includes all final charges and expenses associated with the cost reimbursement portion of the program contract. Mark as "Final".

Submit Copy to:

Name of Area	Original Signature Required Yes	Original Signature Required No	Accepted Method of Submission	# Copies

Women's Health & Education Services Mailbox		Email (preferred), or Fax	1
Email box designated by program	X		

Instructions: Form 269A must have an original signature (scanned email or fax accepted).

Financial Status Reports (FSRs) for Cost Reimbursement HTW Contracts

The HTW program operates using fee-for-service (FFS), and a cost reimbursement award.

The quarterly reports are due 30 days following the end of each quarter of the contract term. The final FSR, 269A, is due within 45 days after the end of the contract term, unless stipulated differently in the contract attachment. HHSC reserves the right to base funding levels, in part, upon the contractor's delivery of direct client services under HTW fee-for-service.

Programmatic Reporting

The HTW Promotion/Outreach Annual Report must be sent to the email box designated by program. The report is due within forty-five (45) days after the end of the contract period (October 15).

CHAPTER 5: PROGRAM PROMOTION AND OUTREACH

Contractors must develop and implement an annual plan to provide community education and program promotion to:

- inform the public of the purpose of the program and available services;

- enhance community understanding of its objectives;
- disseminate basic family planning and women's health care knowledge;
- enlist community support; and
- recruit potential clients for HTW.

The plan should be based on an assessment of the needs of the community and contain an evaluation strategy. Contractors should consider a variety of program promotion and client outreach strategies in accordance with organizational capacity, availability of existing resources and materials, and the needs and culture of the local community. To gauge the efficacy of program promotion and client outreach activities, contractors must:

- Develop an annual Women's Health Programs promotion and client outreach plan that includes outreach/promotion activities for the year;
- Regularly monitor plan implementation;
- Evaluate the plan on an annual basis; and
- Modify program promotion and outreach activities, as needed.

Contractors must submit a one-page Healthy Texas Women Promotion Plan for the contract period within 45 days of the contract start date. The plan should describe the agency's outreach and marketing strategy and include a description of planned activities to reach potential Healthy Texas Women clients. Contractors must submit a Healthy Texas Women Promotion/Outreach Annual Report to the email box designated by program.

SECTION VI – APPENDICES

Appendix I

HTW Income Worksheet – English
HTW Income Worksheet – Spanish

Appendix II

HTW Screening Tool – English
HTW Screening Tool – Spanish

Appendix III

FPP Definition of Income

Appendix IV

MBCC Application Checklist

Appendix V

MBCC Guidelines for Determination of Qualifying Diagnosis

Appendix VI

BCCS Program Resource Guide

Appendix VII

BCCS Resources and Contacts

SECTION VII – FORMS

Form	Title
1810	Healthy Texas Women Promotion Outreach Annual Report
H1867	Healthy Texas Women Program Application Form
1065	BCCS or FPP Eligibility Application
1065S	BCCS or FPP Eligibility Application Spanish
5200	MED-IT New User
5201	MED-IT New Provider Request
1059	Family Planning Program Professional Development Activities Annual Report
1060	Family Planning Promotion and Outreach Annual Report

SECTION VIII – CONTACT US

For questions about the Women's Health Programs including question about the Policy and Procedure Manual:

Phone: 512-776-7796