

**Department of State Health Services
Agenda Item for State Health Services Council
October 5, 2006**

Agenda Item Title: Amend 25 TAC §§61.31-61.33, 61.36, 61.41, And 61.42, Repeal 25 TAC §§61.34, 61.35, And 61.37-61.40, And New §§61.34, 61.37 And 61.39, Rules Relating to Breast and Cervical Cancer Services

Agenda Number: 3d

Recommended Council Action:

For Discussion Only

For Discussion and Action by the Council

Background: Breast and Cervical Cancer Services provides access to high-quality breast and cervical cancer screening and diagnostic services for financially eligible Texas women that are unable to access the same care through other funding sources or programs. Services may include clinical breast examinations and mammograms to screen for breast cancer, and pelvic examinations and Pap tests to screen for cervical cancer. Diagnostic services and case management are also provided for women with abnormal breast or cervical cancer screening results. Services are provided through contracts with nonprofit agencies, local health departments, hospitals, and community health centers.

Summary: The amendments, repeals, and new rules are proposed in response to the four-year review of state agency rules required by Government Code §2001.039. The intended revisions will only change current program structure and implementation as it relates to the collection of program income by contracted providers. Currently, providers are prohibited by rule from collecting co-payments from clients for services performed. The proposed rule language will allow but not require contractors to collect co-payments within the guidelines of department policy and federal law. According to department policy, these payments must be reported to the department as program income and be reinvested in the contracted activities during the fiscal year. Allowing providers to collect co-payments as program income should enable those providers to increase services to the target population of low-income women. These amendments, repeals, and new sections are intended to clarify, update, and streamline the rules, and are not anticipated to be controversial or have significant fiscal impact to the department or local government.

Summary of Stakeholder Input to Date (including advisory committees): Favorable stakeholder input was gathered during a contractor conference call held April 19, 2006. Input will continue to be collected through verbal, written, e-mail and web site communications throughout the process.

Proposed Motion: Motion to recommend HHSC approval for publication of rules contained in agenda item 3d.

Agenda Item Approved by: Mike Montgomery for Evelyn Delgado

Presented by: Margaret Mendez **Title:** Section Manager

Program/Division: Preventive and Primary Care Unit

Contact Name/Phone: Kim Roberts, 458-7796, x2990

Date Submitted

7/3/06

Title 25. Health Services
Part 1. Department of State Health Services
Chapter 61. Chronic Diseases
Subchapter C. Breast and Cervical Cancer Services [**Control Program**]
Amendments §§61.31-61.33, 61.36, 61.41, and 61.42
Repeal §§61.34, 61.35, and 61.37-61.40
New §§61.34, 61.37, and 61.39

PROPOSED PREAMBLE

The Executive Commissioner of the Health and Human Services Commission, on behalf of the Department of State Health Services (department), proposes amendments to §§61.31-61.33, 61.36, 61.41 and 61.42, the repeal of §§61.34, 61.35, and 61.37-61.40, and new §§61.34, 61.37, and 61.39 concerning the provision of breast and cervical cancer services in this state.

BACKGROUND AND PURPOSE

The amendments, repeals, and new sections are necessary to assist the department in the implementation of the federal Breast and Cervical Cancer Mortality Prevention Act of 1990, Public Law 101-354, and its re-authorization, the Women's Health Research and Prevention Amendments of 1998, Public Law 105-340, which establish a program of grants to states, territories, and tribal organizations for early detection and prevention of mortality from breast and cervical cancer. The department, through a cooperative agreement with the Centers for Disease Control and Prevention, provides statewide access to high-quality breast and cervical cancer screening and diagnostic services for financially eligible Texas women who are unable to access the same care through other funding sources or programs.

Government Code, §2001.039, requires that each state agency review and consider for re-adoption each rule adopted by that agency pursuant to the Government Code, Chapter 2001 (Administrative Procedure Act). Sections 61.31-61.42 have been reviewed, and the department has determined that reasons for adopting §§61.31-61.34, 61.36-61.37, 61.39, and 61.41-61.42 continue to exist because rules on this subject are needed. The department also has determined that §§61.35, 61.38, and 61.40 are no longer needed, and that the sections should be repealed. There are breaks in the proposed section numbers, as these sections will be reserved for new rules at a later date.

SECTION-BY-SECTION SUMMARY

Amendments to §§61.31-61.33, 61.36, 61.41, and 61.42 incorporate the current department and program names to be consistent with current terminology used by the department.

An amendment to §61.31 removes language specific to the establishment of requirements by certain entities to allow for more flexibility to receive and utilize funding from additional sources. Additionally, §61.31 has been amended to clarify that case management services are included in the breast and cervical cancer services the department provides.

An amendment to §61.32 clarifies that the department manages the delivery of breast and cervical cancer services in accordance with federal requirements utilizing the established statewide program.

Amendments to §61.33 reflect a change in terminology regarding the providers of breast and cervical cancer services.

The repeal and new §61.34 revise language to clarify client eligibility requirements.

Section 61.35 is proposed for repeal, because the process for selecting and contracting with providers need not be specified by rule.

Amendments to §61.36 allow providers more flexibility to receive and utilize funding from additional sources.

The repeal and new §61.37 remove redundant language and clarify screening requirements for providers.

Section 61.38 is proposed for repeal because quality assurance standards have been included in §61.37 to improve clarity.

The repeal and new §61.39 delete detailed requirements for provision of services that are more appropriate for inclusion in a policy manual.

Section 61.40 is proposed for repeal as redundant because the provisions in that section have been included in §§61.31 and 61.36.

Amendments to §61.41 update terminology concerning the activities performed and the process by which providers receive payment from the department in order to align the rules with changes in programmatic and department policy related to fee-for-service programs.

Amendments to §61.42 allow providers to collect a co-payment from clients for breast and cervical cancer services performed.

FISCAL NOTE

Cindy Jones, Ph.D., R.N., Manager, Preventive and Primary Care Unit, has determined that for each year of the first five years the sections are in effect, there will be no fiscal implications to state or local governments as a result of administering the sections as proposed. The proposed rules change current program structure and implementation only as they relate to the collection of co-payments from clients by participating providers. According to department policy, these payments must be reported to the department as program income and used by providers to perform program services during the fiscal year. Allowing providers to collect co-payments as program income should enable providers to increase services to the target population of low-income women. These amendments, repeals, and new sections are intended to clarify, update, and streamline the

rules, and are not anticipated to be controversial or have significant fiscal impact to the department or local government.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Dr. Jones has also determined that there will be no effect on small businesses or micro-businesses required to comply with the sections as proposed, because neither small businesses nor micro-businesses that are providers of breast and cervical cancer services will be required to alter their business practices in order to comply with the sections. If any providers decide to charge co-payments, some of the clients whom they serve may experience increased economic costs, depending on their household incomes. However, the higher costs for individual clients cannot be estimated because of the different services each could receive, and the number of providers that will adopt a co-payment policy is unknown at this time. There is no anticipated negative impact on local employment.

PUBLIC BENEFIT

Dr. Jones has also determined that for each year of the first five years the sections are in effect, the public benefit anticipated as a result of administering the sections will be continued access to breast and cervical cancer screening and diagnostic services for eligible, low-income Texas women.

REGULATORY ANALYSIS

The department has determined that this proposal is not a “major environmental rule” as defined by Government Code, §2001.0225. “Major environmental rule” is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

TAKINGS IMPACT ASSESSMENT

The department has determined that the proposed sections do not restrict or limit an owner’s right to his or her property that would otherwise exist in the absence of government action and, therefore, do not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted to Kim Roberts, Mail Code 1923, Community Health Services Section, Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756-3189 or by email to kim.roberts@dshs.state.tx.us. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

LEGAL CERTIFICATION

The Department of State Health Services General Counsel, Cathy Campbell, certifies that the proposed rules have been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The proposed amendments, new rules and repeals are authorized by Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001.

The proposed amendments, new rules and repeals affect Government Code, Chapter 531, and Health and Safety Code, Chapter 1001. Review of the sections implements Government Code, §2001.039.

Sections for repeal.

- §61.34. Eligibility for Program Services.
- §61.35. Selection Process.
- §61.37. Program Eligibility Requirements.
- §61.38. Quality Assurance Standards.
- §61.39. Follow-up and Case Management.
- §61.40. Maintenance of Current Services.

Legend: (Proposed Amendments)

Single Underline = Proposed new language

[Bold Print and Brackets] = Current language proposed for deletion

Regular Print = Current language

(No change.) = No changes are being considered for the designated subdivision

§61.31. Purpose. These sections implement requirements and procedures **[established by the federal government, the State of Texas, and the Department of Health (department)]** for the delivery of screening, diagnostic, **[and]** follow-up, and case management services for breast and cervical cancer through the Department of State Health Services **[department's]** Breast and Cervical Cancer Services **[Control Program]**.

§61.32. Federal Authorization and Requirements. The Breast and Cervical Cancer Mortality Prevention Act of 1990 (Act), Public Law 101-354, and its re-authorization, the Women's Health Research and Prevention Amendments of 1998, Public Law 105-340, establish a program of grants to states, territories, and tribal organizations for early detection of and prevention of mortality from breast and cervical cancer. The **[Texas]** Department of State Health Services, through a cooperative agreement with the Centers for Disease Control and Prevention and in compliance with the Act and its reauthorization, manages the delivery of breast and cervical cancer services statewide through Breast and Cervical Cancer Services **[Control Program (program)]**.

§61.33. Providers **[Eligible Applicants]**. Health care providers serving women with incomes at or below 200% of the federal poverty level are eligible to apply as **[participants in the]** Breast and Cervical Cancer Services providers **[Control Program]**. Eligible applicants include, but are not limited to, community health centers, migrant health centers, local and regional health departments, family planning clinics, community cancer centers, hospitals, primary care programs, and other providers of health services to the target and priority populations.

Legend: (Proposed New Rule)

Regular Print: Proposed new language

§61.34. Client Eligibility Requirements.

(a) In order for a woman to be financially eligible for Breast and Cervical Cancer Services, the woman must:

(1) have a family income that does not exceed 200% of the current federal poverty level and

(2) not have access to third-party payment for screening and/or diagnostic services.

(b) A woman age 40 or older that meets financial eligibility criteria is eligible for breast cancer screening and diagnostic services. A woman under age 40 that meets financial eligibility criteria is eligible for breast cancer diagnostic services only.

§§61.34, 61.36-37

(c) A woman age 18 or older that meets financial eligibility criteria is eligible for cervical cancer screening and/or diagnostic services.

Legend: (Proposed Amendments)

Single Underline = Proposed new language

[Bold Print and Brackets] = Current language proposed for deletion

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§61.36. Provider Applicant **[Program]** Requirements. To be funded to provide Breast and Cervical Cancer Services **[Control Program (program) services]**, applicants shall demonstrate:

(1)-(5) (No change.)

(6) evidence of intent to comply with Department of State Health Services **[department]** **[program]** screening policies and guidelines;

(7) (No change.)

(8) evidence of ability to comply with all other department **[program]** standards, policies, and requirements; and

(9) evidence that Breast and Cervical Cancer Services **[program]** funds will not be used to supplant existing funding for similar services. **[; and]**

[(10) evidence that the applicant has received funding for and budgeted the match sources and allowances of nonfederal contributions for the program.]

Legend: (Proposed New Rule)

Regular Print: Proposed new language

§61.37. Screening Requirements. Participating providers shall provide or assure the provision of screening services in accordance with the following requirements:

(1) breast cancer screening shall include a clinical breast examination and a mammogram;

(2) cervical cancer screening shall include a clinical breast examination, pelvic examination, and a Pap test;

(3) mammography and cytological laboratory services shall be delivered in compliance with quality assurance standards specified in the Breast and Cervical Cancer Services policy and procedures manual; and

§§61.37, 61.39, 61.41

(4) abnormal screening results shall be confirmed by diagnostic procedures according to the protocols specified in the Breast and Cervical Cancer Services policy and procedures manual.

§61.39. Follow-up and Case Management Requirements. Participating providers shall:

(1) provide or assure provision of follow-up and case management services that comply with the Breast and Cervical Cancer Services policy and procedure manual; and

(2) ensure that women eligible for services who have abnormal breast or cervical cancer screening or diagnostic results receive follow-up services, including case management, until a diagnosis is reached and/or treatment for cancer is initiated.

Legend: (Proposed Amendments)

Single Underline = Proposed new language

[Bold Print and Brackets] = Current language proposed for deletion

Regular Print = Current language

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§61.41. Payment **[Reimbursement]** for Services.

(a) Payment **[Reimbursement]** for clinical screening and diagnostic services shall be on a fee-for-service basis.

(b) Payment **[Reimbursement]** will be subject to audit by the Department of State Health Services (department). The department **[Breast and Cervical Cancer Control Program (program)]** shall approve all covered procedures and payment **[reimbursement]** rates, which shall not exceed the maximum state Medicare rates **[rate]** for that procedure. A list of procedures approved for payment **[reimbursement]** shall be included in all **[program]** requests for proposals and **[,]** contracts **[, and the program Manual of Operations]**.

(c) In accordance with department policy, providers may be allowed to bill **[The program shall reimburse providers]** for administrative and support services costs associated with the following activities:

(1) (No change.)

- (2) public education and outreach;
- (3) professional [client] education;
- (4) program management;
- (5) coalition and partnership development;
- (6)[(4)] data collection and reporting; and
§61.41-61.42

(7)[(5)] other activities authorized in advance.

(d) In order to bill [be reimbursed] for administrative and support services costs, a provider must request such funding [reimbursement] in its annual proposed budget. Administrative and support services costs [cost reimbursement] shall not exceed 10% of a [service] provider's actual expenditures [budget] for clinical services.

§61.42. Client Co-Payment [Charges]. Participating providers may [not] charge clients a co-payment [fees] for services in accordance with the Breast and Cervical Cancer Services policy and procedures manual [reimbursed by the program].