NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES NOTICE OF PUBLIC HEARING

November 4, 2020 10:00 a.m. Central Time Nebraska State Office Building – Lower Level A 301 Centennial Mall South, Lincoln, Nebraska Phone call information: 888-820-1398; Participant code: 3213662#

The purpose of this hearing is to receive comments on proposed changes to Title 181, Chapter 40 of the Nebraska Administrative Code (NAC) – *Nebraska Breast and Cervical Cancer Program.* The proposed regulations outline the eligibility requirements for women and clinical providers to participate in the Nebraska Breast and Cervical Cancer Program and Wise Woman. The proposed changes include updating definitions; specifying the limitations on services; identifying the conditions for payment of claims; and updating the process for fair hearing procedures. Additional proposed changes update and set out the services allowable to include: breast and cervical cancer screening and diagnostic testing; heart disease screening; and healthy supports.

Authority for these regulations is found in <u>Neb. Rev. Stat.</u> § 81-3117(7).

Due to the current public health crisis, the agency will enforce any Directed Health Measure Order on the size of gatherings that is in effect at the time of the hearing. In order to encourage participation in this public hearing, a phone conference line will be set up for any member of the public to call in and provide oral comments.

Interested persons may provide verbal comments by participating via phone conference line by calling 888-820-1398; Participant code: 3213662#.

Interested persons may attend the hearing and provide verbal or written comments or mail, fax or email written comments, no later than the day of the hearing to: DHHS Legal Services, PO Box 95026, Lincoln, NE 68509-5026, (402) 742-2382 or dhhs.regulations@nebraska.gov, respectively.

A copy of the proposed changes is available online at http://www.sos.ne.gov, or by contacting DHHS at the mailing address or email above, or by phone at (402) 471-8417. The fiscal impact statement for these proposed changes may be obtained at the office of the Secretary of State, Regulations Division, 1201 N Street, Suite 120, Lincoln, NE 68508, or by calling (402) 471-2385.

Auxiliary aids or reasonable accommodations needed to participate in a hearing can be requested by calling (402) 471-8417. Individuals with hearing impairments may call DHHS at (402) 471-9570 (voice and TDD) or the Nebraska Relay System at 711 or (800) 833-7352 TDD at least 2 weeks prior to the hearing.

FISCAL IMPACT STATEMENT

Agency: Department of Health and Human Services			
Title: Special Health Programs	Prepared by: Melissa D. Leypoldt		
Chapter: 40	Date prepared:07/01/2019		
Subject: Rules and Regulations for Nebraska Breast and Cervical Cancer	Telephone:402-471-0314		
Program			

Type of Fiscal Impact:

	State Agency	Political Sub.	Regulated Public
No Fiscal Impact	(🛛)	(🖂)	(🖂)
Increased Costs	(🗆)	(🗆)	(🗆)
Decreased Costs	(🗆)	(🗆)	(🗆)
Increased Revenue	(🗆)	(🗆)	(🗆)
Decreased Revenue	(🗆)	(🗆)	(🗆)
Indeterminable	(🗆)	(🗆)	(🗆)

Provide an Estimated Cost & Description of Impact:

State Agency:

Political Subdivision:

Regulated Public:

If indeterminable, explain why:

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181 NAC 40

TITLE 181 SPECIAL HEALTH PROGRAMS

CHAPTER 40 NEBRASKA BREAST AND CERVICAL CANCER PROGRAM

001. <u>SCOPE AND AUTHORITY. These regulations govern and implement Nebraska Revised</u> <u>Statute (Neb. Rev. Stat.) §§ 71-7003.01 and 71-7010 by setting standards for client and provider</u> <u>eligibility and participation.</u>

002. DEFINITIONS. The following definitions apply to this chapter.

<u>002.01 PROVIDER. A provider offering screening, or diagnostic services for breast cancer, cervical cancer or cardiovascular services and who is listed as a participating provider.</u>

<u>002.02 CLIENT. An individual who has requested assistance in receiving education or</u> services for breast cancer, cervical cancer, or cardiovascular disease screening, follow up, diagnostics, treatment or healthy supports, or is receiving such services.

002.03 COMPLETE ENROLLMENT FORM. An application provided by the Department which contains all the requested information and medical release form, with attestation to its truthfulness and completeness, all required signatures, submitted with all documentation is a complete application.

<u>003.</u> <u>ELIGIBILITY.</u> Providers and clients must meet statutory requirements and the following requirements.

003.01 CLIENT. Eligibility criteria for the screening and diagnostic programs are as follows:

- (A) <u>SCREENING. To participate in the screening an individual must submit a complete</u> <u>enrollment form and meet the following:</u>
 - (i) Be a woman between the ages of 40 74 years old;
 - (ii) <u>Have an income at or below 225% of the Federal Poverty Guidelines as of the effective date of the enrollment date; and</u>
 - (iii) Not have health coverage that would pay for preventive services.
- (B) <u>DIAGNOSTIC.</u> To participate in the Diagnostic Program, an individual must submit a complete enrollment form and meet the following:
 - (i) Have an abnormal screening result within the last six months; and
 - (ii) Be 18 -74 years of age for breast cancer diagnostics; or
 - (iii) Be 21 -74 years of age, for cervical cancer diagnostics; and
 - (iv) <u>Have an income at or below 225% of the Federal Poverty Guideline as of the effective date of the enrollment date; and</u>

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(v) Not have private, Medicare, or Medicaid insurance coverage that provides complete coverage for allowable program services.

003.02 PROVIDER. To participate as a provider in the Nebraska Breast and Cervical Cancer Program, a provider must meet the requirements in Neb. Rev. Stat. § 71-7010 and the following:

- (A) Service providers must be licensed by the Department, or hold equivalent credentials in another state, and perform services in compliance with requirements set out in 42 United States Code (U.S.C.) §300m as of the effective date of this chapter;
- (B) Submit a complete enrollment form;
- (C) Meet-the standards set out in enrollment form;
- (D) Submit invoices and follow billing and payment procedures as set out in 181 Nebraska Administrative Code (NAC) 004; and
- (E) Accept payment made through the program as payment in full and not bill clients for Services covered by the program for which they were eligible at the time of service.

<u>004.</u> <u>SERVICES. Covered services include those services specified in 42 U.S.C. §300k and 42 U.S.C. §300m as of the effective date of this chapter.</u>

<u>005.</u> <u>APPROVAL AND PAYMENT. Claims may be approved for payment when all the following conditions are met:</u>

- (A) The client was approved for participation in the Program when the service was provided;
- (B) The services provided are for covered services as described in 181 NAC 004;
- (C) The Provider has agreed to provide reports of findings and recommendations which are necessary to compile cancer surveillance data and reports to the funder, the Centers for Disease Control and Prevention. Additionally, the provider shall ensure that the program receives the required documentations specified in the Provider Manual as of the date of this regulation;
- (D) Invoice procedures outlined in the Provider Manual as of the effective date of this regulation are complied with; and
- (E) All other claims and documentations pursuant to the program policy as set out in the Provider Manual as of the date of this regulation, are submitted.

005.01 PAYOR OF LAST RESORT. The Program is a payer of last resort. Primary insurance providers must be invoiced first and have paid on a client's behalf before an invoice is sent to the program for payment by a provider.

006. LIMITS. The following limitations shall apply:

- (A) Pursuant to 42 U.S.C. §300n, this program shall not be accessed to provide inpatient hospital services or cancer treatment for any individual.
- (B) Provider payment shall be made based upon availability of funds and number of services provided to clients;

<u>007.</u> FAIR HEARING. If an applicant is denied participation in the program the applicant may request a fair hearing. The request must be in writing and filed with the Department within thirty (30) days of the mailing date on the written notice from the Department. The request must:

- (A) Include a brief summary of the Department's action being challenged;
- (B) Describe the reason for the challenge; and

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(C) Be sent to the Director of the Nebraska Department of Health & Human Services, Division of Public Health.

007.01 PROCEDURE. The hearing is conducted in accordance with 184 NAC 1.

NEBRASKA DEPARTMENT OF HEALTH TITLE 181, NEBRASKA ADMINISTRATIVE CODE, CHAPTER 40 REGULATIONS GOVERNING THE SCREENING MAMMOGRAPHY PROGRAM

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Title 181 - Nebraska Department of Health

Chapter 40 - Regulations Governing the Screening Mammography Program

001 DEFINITIONS. For the purposes of these regulations, the following definitions shall apply.

- 001.01 Asymptomatic. Asymptomatic shall mean no physical finding related to the breast.
- 001.02 Department. Department shall mean the Department of Health.
- 001.03 False Negative Result. False negative result shall mean a mammogram which indicates no possible cancer when a cancer exists
- 001.04 False Positive Result. False positive result shall mean a mammogram, which indicates a possible cancer when none exists.
- 001.05 Household Income. Household income shall mean the personal family income of the applicant, which shall include the total annual cash receipts before taxes from all sources of the applicant and any other person related by birth, marriage, or adoption who lives with and contributes to the support of the applicant.
- 001.06 Mammogram. Mammogram shall mean the X-ray resulting from mammography.
- 001.07 Mammogram Supplier. Mammogram supplier shall mean a public, private, forprofit, or not-for-profit agency or health care facility that provides mammography.
- 001.08 Mammography. Mammography shall mean radiological examination of the breast for the purpose of obtaining a mammogram which enables a physician to assess the presence, size, location, and extent of cancerous or potentially cancerous tissue.
- 001.09 Participant. Participant shall mean a woman whose application is approved by the department to receive screening mammography under the program described in these regulations.

- 001.10 Professional Component. Professional component shall mean the interpretation of a screening mammogram and a written report regarding the interpretation provided by a mammogram supplier.
- 001.11 Screening Mammogram. Screening mammogram shall mean the X-ray resulting from screening mammography.
- 001.12 Screening Mammography. Screening mammography shall mean radiological examination of the breast of asymptomatic women for the early detection of breast cancer, which examination shall include (a) a cranio-caudal and a medial lateral oblique view of each breast and (b) a licensed radiologist's interpretation of the results of the procedure. Screening mammography shall not include diagnostic mammography, additional projections required for lesion definition, breast ultrasound, or any breast interventional procedure.
- 001.13 Technical Component. Technical component shall mean mammography and all other services provided by a mammogram supplier.
- 001.14 X-ray System Operator. X-ray system operator shall mean a person other than a licensed practitioner or a certified physician assistant who operates an X-ray system under the supervision of a licensed practitioner.

002 SCOPE OF REGULATIONS. These regulations are promulgated under the authority of and in compliance with Neb. Rev. Stat. §§71-7001 to 71-7013. The purpose of these regulations is to establish participant eligibility and supplier certification criteria and application processes, a schedule of fees and income eligibility guidelines for participants, procedures for obtaining screening mammography, supplier reimbursement rates and process, supplier certification denial, revocation, suspension and reinstatement, and procedures for the appeal of adverse actions by the Department.

003 MAMMOGRAPHY SCREENING. The department may offer to women a screening mammography program as follows, except that the department shall not pay for screening mammography for women who have public or private insurance that covers screening mammography, whose personal family income exceeds the maximum income guidelines described in Section 006 of these regulations, or who are eligible for mammography screening under any federal or state health benefit program.

- 003.01 For asymptomatic women over thirty years of age but under fifty years of age, one screening mammogram will be reimbursed after at least eleven months have passed following the month in which the last screening mammogram was performed if the woman has a personal history of breast cancer or has a mother or sister who has or had pre-menopausal breast cancer; or
- 003.02 For asymptomatic women over thirty-four years of age but under forty years of age, one screening mammogram will be reimbursed; or
- 003.03 For asymptomatic women over thirty-nine years of age but under fifty years of age, reimbursement may be made for a screening mammogram performed after at least twenty-three months have passed following the month in which the last screening mammogram, was performed if the woman has no personal history of breast cancer; or
- 003.04 For asymptomatic women over forty-nine years of age but under sixty-five years of age, reimbursement may be made for a screening mammogram performed after at least eleven months have passed following the month in which the last screening mammogram was performed, and
- 003.05 The applicant for participation in the screening mammography program meets the program and financial eligibility criteria set forth in Sections 005 and 006 below.

004 AVAILABILITY OF FUNDS. Participation in the screening mammography program is subject to the availability of funds in the Mammography Screening Cash Fund. In the event funds are not available, applicants who meet the eligibility criteria will be placed on a waiting list in order of date of receipt of the application by the department. Waiting list applicants must meet eligibility standards at the time funds become available to reimburse for screening mammography services. Moved to section 006.2 as modified

005 PARTICIPANT ELIGIBILITY. To be eligible to obtain screening mammography as provided by this program, an applicant must meet the following criteria. Moved to section 003 as modified

- 005.01 The applicant must be a resident of Nebraska;
- 005.02 The applicant's household income must be within the income eligibility guidelines set forth in Section 006 of these regulations;
- 005.03 The applicant must provide the name of a physician for follow-up consultation or treatment;

- 005.04 The applicant must be in one of the categories set forth in Subsection 003.01 through 003.04 of these regulations;
- 005.05 The applicant must pay any fee required pursuant to Section 006 of these regulations.

006 PARTICIPANT INCOME ELIGIBILITY GUIDELINES AND SLIDING FEE SCHEDULE in order to participate in the screening mammography program, applicants must meet the income eligibility guidelines and sliding fee schedule for screening mammography set forth below. The applicant must pay the fee, if any, to the Department before the Department may issue a certificate of eligibility. Moved to section 003 as modified

- 006.01 The United States Department of Health and Human Services federal poverty income guidelines in effect at the time of application are the income eligibility guidelines for participation in the screening mammography program.
- 006.02 The sliding fee schedule for participation in the program is as follows:
 - 006.02A An applicant with income at 100 percent or less of the guidelines shall pay no fee.
 - 006.02B An applicant with income between 100 percent and 200 percent of the guidelines shall pay one-half of the mammogram reimbursement rate established in Section 011.
 - 006.02C An applicant with income between 200 percent and 225 percent of the guidelines shall pay the full mammogram reimbursement rate established in Section 011.
 - 006.02D An applicant with income over 225 percent of the guidelines is not eligible to participate in the screening mammography program.

007 CERTIFICATE OF ELIGIBILITY. The Department may issue certificates of eligibility to participate in the screening mammography program. Certificates of eligibility are valid for one mammogram. The certificate is not transferable to another person. The certificate of eligibility must be presented to the mammogram supplier within ninety days from the date of issuance by the Department.

008 PARTICIPANT APPEAL RIGHTS. If the department denies an application for participation in the screening mammography program, the applicant shall have the right to a hearing in accordance with the Administrative Procedure Act and Title 184, Nebraska Administrative Code, Chapter 1, Rules of Practice and Procedure of the Department of Health. The Department shall include a notice of the right to a hearing with the notification of denial of the application. Moved to section 007 as modified

009 SUPPLIER CERTIFICATION ELIGIBILITY. To be certified by the department as a mammogram supplier in this program the supplier applicant must meet the following criteria.

- 009.01 The supplier applicant must be certified by the United States Department of Health and Human Services to provide screening mammography as prescribed in Title 42, Code of Federal Regulations, Parts 405, 410, 411, 413, and 494.
- 009.02 The supplier applicant must present proof of providing screening mammography in Nebraska, together with a statement by the physician to the effect that he or she provides to the applicant an interpretation of the image or films produced by the radiologic procedure.
- 009.03 The supplier applicant agrees to accept as payment in full for both the technical and professional components the reimbursement rate prescribed in Section 011 of these regulations.
- 009.04 The supplier applicant agrees to provide mammography screening in conformance with the conditions of the federal certification for screening mammography.
- 009.05 The supplier applicant agrees to provide to the department a written report on the interpretation of the .results of the screening mammogram procedure.
- 009.06 The supplier applicant agrees to comply with federal grants management requirements as applicable to the supplier in the event that federal grant funds are part of the program.
- 009.07 The supplier applicant must submit a signed, complete application on the form provided by the department, a copy of which is attached as Attachment 1 and incorporated in these regulations by this reference.

010 CONDITIONS OF PARTICIPATION FOR MAMMOGRAM SUPPLIER. Once approved by the department to participate as a screening mammogram supplier, the supplier must meet the following conditions of participation.

- 010.01 The supplier shall comply with all applicable federal, state, and local laws and regulations pertaining to radiological services and screening mammography.
- 010.02 The supplier shall maintain the Medicare certification to provide screening mammography.
- 010.03 The supplier shall provide screening mammography, including a physician's interpretation of the images or films produced by the radiologic procedure.
- 010.04 The supplier shall accept as payment in full the reimbursement rate for both the technical and professional component set forth in section 011 of these regulations.
- 010.05 The supplier shall provide mammography screening in conformance with the conditions of the Medicare certification for screening mammography.
- 010.06 The supplier shall provide to the department a written report on the interpretation of the results of the screening mammogram procedure.
- 010.07 The supplier shall comply with federal grant management requirements as applicable to the supplier.
- 010.08 The supplier shall ensure that an interpreting physician prepares and signs a written report and forwards the report and the original images or films to the supplier for inclusion in the participant's medical record.
- 010.09 The supplier shall maintain confidential records containing all information pertaining to screening mammography provided under these regulations.

011 SCREENING MAMMOGRAPHY SUPPLIER REIMBURSEMENT RATE. Reimbursement for each mammogram provided under the screening mammography program shall be in an amount equal to the Medicare reimbursement rate for screening mammography which is in effect at the time the service is provided. 012 DENIAL, SUSPENSION OR REVOCATION OF MAMMOGRAM SUPPLIER CERTIFICATION. In addition to denial of the application for certification for failure to satisfy the eligibility criteria, the Department may deny, suspend, or revoke the certification of a mammogram supplier for violations of Neb. Rev. Stat. §71-7004 and Section 009 and 010 of these regulations. The denial, suspension, or revocation shall become final thirty days after the mailing of the notice unless the mammogram supplier, within such thirty-day period, requests in writing a hearing. The notice shall advise of the right to hearing. The mammogram supplier shall be given a hearing before the department according to the Administrative Procedure Act and Title 184, Nebraska Administrative Code, Chapter 1.

013 SUPPLIER REINSTATEMENT. Mammogram suppliers whose certification has been suspended or revoked may apply for reinstatement subject to the following conditions. Applicants for reinstatement shall submit a signed, completed application on the form provided by the department, a copy of which is attached as Attachment 2 and incorporated in these regulations by reference.

- 013.01 The applicant for reinstatement shall satisfy the eligibility criteria contained in section 009 of these regulations.
- 013.01 The applicant shall provide to the department the following information.
 - 013.01A The action and the date it was taken;
 - 013.01B The reason for the suspension or revocation;
 - 013.01C The corrective action taken by the applicant;
 - 013.01D Two verified recommendations regarding the activities of the applicant since the date of the suspension and the corrective action taken, and a statement of the relationship of the applicant to the person making the recommendation.
- 013.02 A mammogram supplier whose certification has been suspended may apply for reinstatement of such certification at any time.
- 013.03 A mammogram supplier whose certification has been revoked may apply for reinstatement of such certification after a period of not less than two years has elapsed from the date of revocation.

013.04 A mammogram supplier whose application for reinstatement is denied by the department has the right to a hearing according to the Administrative Procedure Act and Title 184, Nebraska Administrative Code, Chapter 1. The notice of denial shall include a notice of the right to hearing.