townhall.virginia.gov

Proposed Regulation
Agency Background Document

Agency name	DEPT OF MEDICAL ASSISTANCE SERVICES
Virginia Administrative Code (VAC) citation(s)	12 VAC 30-50-220
Regulation title(s)	Other Diagnostic, Screening, Preventive, and Rehabilitative Services, I.E., Other Than Those Provided Elsewhere in This Plan
Action title	LDCT Lung Cancer Screening
Date this document prepared	March 13, 2017

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief Summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

In response to a legislative mandate (Chapter 780 of the 2016 Acts of the Assembly, Item 306.OOOO), and in order to reduce lung cancer morbidity and mortality in Virginia, this proposed regulation provides Medicaid coverage of annual LDCT lung cancer screening as a preventive measure, in the absence of symptoms, for at-risk beneficiaries.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

DMAS = Department of Medical Assistance Services

Legal Basis

Please identify the (1) the agency (includes any type of promulgating entity) and (2) the state and/or federal legal authority for the proposed regulatory action, including the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable. Your citation should include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

The *Code of Virginia* (1950) as amended, § 32.1-325, grants to the Board of Medical Assistance Services the authority to administer and amend the Plan for Medical Assistance. The *Code of Virginia* (1950) as amended, § 32.1-324, authorizes the Director of DMAS to administer and amend the Plan for Medical Assistance according to the Board's requirements. The Medicaid authority as established by § 1902 (a) of the *Social Security Act* [42 U.S.C. 1396a] provides governing authority for payments for services.

The 2016 *Acts of Assembly*, Chapter 780, Item 306.OOOO stated, "The Department of Medical Assistance Services (DMAS), in consultation with the appropriate stakeholders, shall seek federal authority via a state plan amendment to cover low-dose computed tomography (LDCT) lung cancer screenings for high-risk adults. The department shall promulgate emergency regulations to implement this amendment within 280 days or less from the enactment of this Act."

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

At present, DMAS does not cover LDCT screening for adults as a preventive service. There is evidence that this policy puts adults at increased risk of developing advanced-stage lung cancer. This regulatory action will permit DMAS to cover LDCT screenings for at-risk adults, thereby enabling DMAS to help make further reductions in lung cancer morbidity and mortality. Additionally, DMAS would align itself with established federal recommendations which support LDCT screening.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of changes" section below.

DMAS has determined that this regulatory action is needed to increase the potential to diagnose lung cancer at earlier stages and reduce incidences of advanced-stage lung cancer, and to help reduce the costs associated with lung cancer.

The United States Preventive Services Task Force (USPSTF) – an independent panel of experts authorized by Congress to make recommendations about specific preventive services for patients with no signs or symptoms of disease – issued a statement in 2013 giving LDCT scans a grade of "B", recommending that certain individuals get an LDCT scan every year. Criteria include individuals between the ages of 55 and 80 years who are current smokers, have quit smoking within the last 15 years, or have a history of smoking at least one pack of cigarettes per day for 30 or more years[1].

This action serves to align Medicaid coverage with the coverage provided by Medicare and commercial health plans; achieve consistency among the FFS and MCO programs; and bring DMAS in line with USPSTF recommendations.

The regulations affected by this action are the Other Diagnostic, Screening, Preventive, and Rehabilitative Services, I.E., Other Than Those Provided Elsewhere in This Plan (12 VAC 30-50-220). Sections of the State Plan for Medical Assistance (and related regulations) recommended for modification are as follows:

BACKGROUND:

Lung cancer is the second most common cancer in both men and women, and it is by far the leading cause of cancer deaths among both genders. One in thirteen men and one in sixteen women will be diagnosed with lung cancer.[2] Each year, more people die of lung cancer than of colon, breast, and prostate cancers combined.[3] Lung cancer accounts for almost 27% of all cancer deaths nationwide.[4]

Nationally, individuals with lung cancer have a five-year relative survival rate of 54 percent if cancer is diagnosed in its earliest (localized) stage.[5] Unfortunately, most lung cancers have spread widely and are at an advanced stage by the time that they are first detected, making them

[1] Simon, Stacy. "US Task Force Makes Recommendations for Lung Cancer Screening." American Cancer Society News Center. Jul 30, 2013.
[2] Surveillance, Epidemiology, and End Results (SEER) Stat Fact Sheets: Lung and Bronchus Cancer.
[3] "Lung Cancer Prevention and Early Detection." American Cancer Society. Feb. 6, 2015.
[4] SEER Stat Fact Sheets: Lung and Bronchus Cancer.
[5] American Cancer Society. "Cancer Facts & Figures 2014."

very difficult to treat or cure. In Virginia, only 19% of lung cancers were diagnosed at the localized stage between 2007 and 2011.[6]

With advanced treatments and preventive screening technologies, the five-year survival rate of lung cancer has reached its highest level since 1975.[7] In particular, LDCT can be used to screen for those at high risk for lung cancer and help detect cancer earlier, thus lowering the risk of death. These screenings are safe for the patient, using lower amounts of radiation than a standard chest scan and not requiring the use of intravenous contrast dye.[8]

In a large clinical trial, (the National Lung Screening Trial) compared LDCT screenings to standard chest X-rays in people at high risk of lung cancer to ascertain if these scans could help lower the risk of dying from lung cancer. The NLST concluded that LDCT scans provided more detailed pictures than chest x-rays and are better at finding small abnormalities in the lungs.[9] On average, 24% of LDCT screenings were positive, compared to approximately 7% of chest X-rays. Additionally, certain cancer cells were detected at the earliest stage more frequently by LDCT screenings than by standard chest X-rays.[10] After several years, the study found that people who got LDCT had a 16% lower chance of dying from lung cancer than those who got chest x-rays, and 7% were less likely to die from any cause than those who got chest x-rays.[11]

Issues

Please identify the issues associated with the proposed regulatory action, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.

The United States Preventive Services Task Force (USPSTF) estimates that a minimum of 20,000 lives can be saved each year through these preventive screenings. Nineteen percent of adults in Virginia were current smokers over the last several years compared to the national average of 17%.[12] Additionally, according to CMS, nationwide 37% of Medicaid insured individuals smoke with total Medicaid expenditures attributable to smoking of nearly $22 billion annually, representing 11% of all expenditures.[13] According to a Quit Now report, approximately 25% of Medicaid insured individuals in Virginia were current smokers in 2015, a figure that has been as high as 27% in the past three fiscal years.[14]

---

[6] Virginia Cancer Registry. Based on combined 2007-2011 data. Incidence rates are age-adjusted to the 2000 U.S. standard population; Percent of Local Stage cancers reported using the Derived Summary Staging System.
[7] SEER Stat Fact Sheets: Lung and Bronchus Cancer.
[8] "Lung Cancer Prevention and Early Detection." American Cancer Society. Feb. 6, 2015.
[9] "Lung Cancer Prevention and Early Detection." American Cancer Society. Feb. 6, 2015.
[10] NIH, National Cancer Institute. National Lung Screening Trial, NLST Study Facts. Sep. 8, 2014.
[11] "Lung Cancer Prevention and Early Detection." American Cancer Society. Feb. 6, 2015.
[12] U.S. Department of Health & Human Services, Centers for Disease Control & Prevention. *Behavioral Risk Factor Surveillance System Survey Data*. 2012.
[13] http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Tobacco.html.
[14] QUIT NOW Virginia, Tobacco Users by Health Plan monthly report. June 2013-2015.

DMAS currently covers LDCT for adults when it is deemed medically necessary (i.e. symptoms present). As a result, lung cancer in the Medicaid population can go undetected until its third and fourth stages when treatment is most costly and morbidity is at its highest. Nationwide, only 16% of lung cancers are stage one (localized) at the time of diagnosis when the five-year survival rate is highest (nearly 55%), while 22% are stage two (having spread regionally) and 57% are stage three (having spread distantly). Tragically, the five-year survival rate is only 4% for stage three lung cancer and just over 27% for stage two.[15]

DISCUSSION:

In Virginia, there were 3,041 inpatient hospitalizations for lung cancer in 2012 (non-Medicaid as well as Medicaid) at a total cost of about $167 million. The average length of stay was 6.5 days and the average cost per stay was $55,122.[16] Moreover, because many studies only examine direct medical costs incurred during hospitalization, these figures under-estimate the true economic consequences of undetected lung cancer.

By covering LDCT screenings as a preventive service, DMAS can help reduce lung cancer morbidity and mortality in Virginia. The procedure is safe, with no adverse effects to the recipient.

To establish the population that would benefit from preventive LDCT screenings, DMAS begins with the at-risk age range from 55-80. Since Medicare coverage (which begins at age 65) includes this service as a preventive measure, we can shorten the range to ages 55-64. For the past three state fiscal years, Virginia's average monthly Medicaid enrollment in this age range was approximately 21,684.[17] Next, given that nearly 25% of Medicaid beneficiaries are current smokers,[18] we can assume the at-risk population to be roughly 5,421.

Requirements More Restrictive Than Federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no requirements in this regulation that are more restrictive than applicable federal requirements.

[15] SEER Stat Fact Sheets: Lung and Bronchus Cancer.
[16] Virginia Department of Health. Virginia Health Information Hospital Discharge Patient-Level Dataset, 2012.
[17] Virginia Department of Medical Assistance Services, Budget & Contract Management Division, internal month end files, 2012-2015.
[18] QUIT NOW Virginia, Tobacco Users by Health Plan monthly report. June 2013- 2015.

Localities Particularly Affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

No localities will be particularly affected, as this regulation will apply statewide.

Public Participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

The agency is seeking comments on this regulatory action, including but not limited to: ideas to be considered in the development of this proposal, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation.

The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping, and other administrative costs; the probable effect of the regulation on affected small businesses; and the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**), or by mail, email, or fax to Karen Thomas (804) 225-2874), Office of Chief Medical Officer, DMAS, 600 East Broad Street, Suite 1300, Richmond, VA 23219; fax (804) 786-1680; Karen.Thomas@dmas.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last day of the public comment period.

A public hearing will not be held following the publication of the proposed stage of this regulatory action.

Economic Impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including: **a) fund source / fund detail; and** **b) a delineation of one-time versus on-going expenditures**	FY 2017GF: ($51,841) FY 2018 GF: ($59,325)
Projected cost of the new regulations or changes to existing regulations on localities.	There is no cost to localities.

Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	Members within the allowed age range and criteria. Entities likely to be affected: potential increase in the utilization of hospitals and out-patient scanning centers. The volume is unknown at this time.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	No small businesses are expected to be affected.
All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.	There are no reporting, recordkeeping, or administrative costs required for compliance by small businesses. There are no costs related to the development of real estate.
Beneficial impact the regulation is designed to produce.	The regulation is designed to promote screening tests performed for prevention or early detection of illness or disability. These are tests performed to find disease at its earliest and most treatable stage, prior to symptoms appearing. This screening may allow for early treatment and prevention of more costly treatment options, thereby increasing health care savings. The screening along with early treatment can potentially lead to decreased morbidity/mortality related to the illness.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

No alternatives would meet the requirements of the legislative mandate.

Regulatory Flexibility Analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

This regulatory action does not establish any compliance or reporting requirements or performance standards for small businesses.

Family Impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

These changes do not strengthen or erode the authority or rights of parents in the education, nurturing, and supervision of their children; nor encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents. It does not strengthen or erode the marital commitment, and does not increase or decrease disposable family income.

Public Comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

No comments were submitted during the Emergency/NOIRA public comment period.

Detail of Changes

Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please list separately: (1) all differences between the ***pre****-emergency regulation and this proposed regulation; and 2) only changes made since the publication of the emergency regulation.*

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, and likely impact of proposed requirements
12 VAC 30-50-220		LDCT preventive screenings are not currently covered.	Establishes LDCT screenings as permissible based on age and smoking status/history. Specifies that DMAS will cover LDCT screenings for at-risk adults, thereby enabling DMAS to help make further reductions in lung cancer morbidity and mortality, and align DMAS with established federal recommendations which support LDCT screening.

The following changes were made between the emergency regulation and the proposed regulation:

- DMAS changed the screening age parameters from 55-79 years to 55-80 years, to align with the USPSTF guidelines.