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Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) 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	November 1, 2016

This form is used when an agency wishes to promulgate an emergency regulation (to be effective for up to eighteen months), as well as publish a Notice of Intended Regulatory Action (NOIRA) to begin the process of promulgating a permanent replacement regulation. 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 of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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 emergency 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
EPSDT = Early and Periodic Screening, Diagnosis, and Treatment (EPSDT)
MRI = Magnetic Resonance Imaging
MRA = Magnetic Resonance Angiography
CAT= Computerized Axial Tomography
CTA = Computed Tomography Angiography
PET = Positron Emission Tomography

Emergency Authority

The APA (Code of Virginia § 2.2-4011) states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of subdivision A. 4. of § 2.2-4006. Please explain why this is an emergency situation as described above, and provide specific citations to the Code of Virginia or the Appropriation Act, if applicable.

Section 2.2-4011 of the *Code of Virginia* states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of *Code of Virginia* §2.2-4006(A)(4).

The 2016 *Acts of Assembly*, Chapter 780, Item 306.OOOO states, "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."

The Governor is hereby requested to approve this agency's adoption of the emergency regulations entitled LDCT Lung Cancer Screening (12 VAC 30-50-220) and also authorize the initiation of the regulation promulgation process provided for in § 2.2-4007 of the *Code*.

Legal Basis

Other than the emergency authority described above, please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and 2) the promulgating entity, i.e., agency, board, or person.

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.

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

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.

Need

Please describe the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

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 79 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 would align Medicaid coverage with the coverage provided by Medicare and commercial health plans, as well as achieve consistency among the FFS and MCO programs. DMAS would be in line with USPSTF recommendations as well, by enacting this emergency regulation.

Substance

Please describe any changes that are proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate. Set forth the specific reasons the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of Virginians.

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 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

[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."
[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.

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]

ISSUE:

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]

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]

Since 2010, Virginia covered 54,401 medically necessary LDCT symptomatic screenings at a total cost of approximately $1.65 million. An annual breakdown of medically necessary LDCT scans and annual costs appears in ***Table 1***

Table 1: Number of Medically Necessary LDCT Scans Covered by DMAS

STATE FISCAL YEAR	CLAIMS	RECIPIENTS	TOTAL COST	COST PER CLAIM
2010	5,593	3,240	$174,599	$31

[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.
[15] SEER Stat Fact Sheets: Lung and Bronchus Cancer.

to the right. Currently, a history of smoking alone does not allow the beneficiary to meet DMAS medical necessity criteria for LDCT screening.

2011	8,722	5,009	$243,451	$28
2012	9,987	5,312	$272,765	$27
2013	9,736	5,727	$298,574	$31
2014	10,797	6,205	$331,421	$31
2015	9,566	5,919	$326,853	$34
Average	**9,067**	**5,235**	**$274,611**	**$30**

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.

Potential Costs Associated with Expanded Coverage

The cost of DMAS covering LDCT scans as a preventive measure for at-risk adults is difficult to determine. The incidence of undetected lung cancer is, by definition, difficult to judge. A range of projected costs, however, can be established with the following set of assumptions that apply the reported percent of the Medicaid population who smoke to the number of Virginia's Medicaid beneficiaries in the appropriate age range.

First, to establish the population that would benefit from preventive LDCT screenings, DMAS begins with the at-risk age range from 55-79. 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.

Second, DMAS must establish the cost of covering this service by looking to the amount that the Dept. currently reimburses providers for administering this service when medically necessary. This reimbursement amount varies by procedure code, and reimbursement amounts to providers can include facility fees. Professional fees alone range from $44.53 to $84.42. When facility fees are included, the reimbursement amount ranges from $166.67 to $325.61.

[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.

Multiplying the physician and/or facility reimbursement amount by the total the number of at-risk beneficiaries in the various uptake groups will provide a projected cost to the Commonwealth at various levels of uptake. These operations are summarized in ***Tables 2 and 3*** that follow. They include both fee-for-service and managed care claims.

Table 2 – Projected Costs of LDCT Screening Coverage by Procedure Code (Facility and Professional Fees Combined)

PROCEDURE CODE	FEE	100% UPTAKE	100% COST	75% UPTAKE	75% COST	50% UPTAKE	50% COST	25% UPTAKE	25% COST
71250	$166.67	5,421	$903,518	4,066	$677,639	2,711	$451,759	1,355	$225,880
71260	$208.73	5,421	$1,131,525	4,066	$848,644	2,711	$565,763	1,355	$282,881
71270	$251.71	5,421	$1,364,520	4,066	$1,023,390	2,711	$682,260	1,355	$341,130
71275	$325.61	5,421	$1,765,132	4,066	$1,323,849	2,711	$882,566	1,355	$441,283

Table 3 – Projected Costs of LDCT Screening Coverage by Procedure Code (Professional Fees Only)

PROCEDURE CODE	FEE	100% UPTAKE	100% COST	75% UPTAKE	75% COST	50% UPTAKE	50% COST	25% UPTAKE	25% COST
71250	$44.53	5,421	$241,397	4,066	$181,048	2,711	$120,699	1,355	$60,349
71260	$54.73	5,421	$296,691	4,066	$222,518	2,711	$148,346	1,355	$74,173
71270	$60.30	5,421	$326,886	4,066	$245,165	2,711	$163,443	1,355	$81,722
71275	$84.42	5,421	$457,641	4,066	$343,231	2,711	$228,820	1,355	$114,410

Under these assumptions and calculations, the projected cost to DMAS could range from $60,349 to just under $1.8 million per year. Since 2005, DMAS has spent nearly $648 million on lung cancer treatment, an amount exceedingly more costly than covering the screening as a preventive measure at the 100% uptake level. Moreover, LDCT screenings may defray future costs associated with treatment of lung cancer in the form of reduced hospitalizations, emergency room visits, outpatient physician visits, medication, durable medical equipment, etc., and support a higher quality of life for individuals with lung cancer.

For MCOs to cover the LDCT screening, a capitation rate adjustment would need to be made. Costs in the managed care sector of Virginia Medicaid would likely be small and may be offset by avoided costs of disease treatment.

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.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

No other alternatives would meet the requirement of the General Assembly mandate.

Public Participation

Please indicate whether the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public meeting is to be held to receive comments. Please also indicate whether a Regulatory Advisory Panel or a Negotiated Rulemaking Panel has been used in the development of the emergency regulation and whether it will also be used in the development of the permanent regulation.

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.

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, but may decrease disposable family income depending upon which provider the recipient chooses for the item or service prescribed.