



# COMMONWEALTH of VIRGINIA

*Office of the Attorney General*

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Glenn A. Youngkin  
Attorney General

**TO:** EMILY MCCLELLAN  
Regulatory Supervisor  
Virginia Department of Medical Assistance Services

**FROM:** USHA KODURU *UK*  
Assistant Attorney General

**DATE:** August 26, 2022

**SUBJECT:** Final/Exempt Regulations – Clinical Trials (5948/9604)

I have reviewed the attached exempt final regulations regarding clinical trials. You have asked the Office of the Attorney General to review and determine if the Department of Medical Assistance Services (“DMAS”) has the legal authority to amend the regulations and if the regulations comport with state and federal law.

The changes in these regulations reflect changes in federal law and changes in wording or style. Based on my review, it is my view that the Director of DMAS, acting on behalf of the Board of Medical Assistance Services, under Virginia Code §§ 32.1-324 and 325, has the authority to amend these regulations, subject to compliance with the provisions of Article 2 of the Administrative Process Act (“APA”) and has not exceeded that authority. Based on the foregoing, it is my view that the amendments to these regulations are exempt from the procedures of Article 2 of the APA under Virginia Code §§ 2.2-4006(A)(4)(c).

It is my understanding that the proposed changes will amend the State Plan. It is my understanding that any approval necessary from the Centers for Medicare and Medicaid Services (“CMS”) has either been obtained or is not needed because the regulatory changes are necessary to reflect the changes made by CMS to 1905(a) of the Social Security Act. If you have any questions, please contact me at 786-4074.

cc: Kim F. Piner, Esq.

Attachment

12VAC30-50-20 Services provided to the categorically needy without limitation

The following services as described in Part III (12VAC30-50-100 et seq.) of this chapter are provided to the categorically needy without limitation:

1. Nursing facility services (other than services in an institution for mental diseases) for individuals 21 years of age or older.
2. Services for individuals 65 years of age or older in institutions for mental diseases: inpatient hospital services; skilled nursing facility services; and services in an intermediate care facility.
3. Intermediate care facility services (other than such services in an institution for mental diseases) for persons determined, in accordance with § 1902(a)(31)(A) of the Social Security Act (the Act), to be in need of such care, including such services in a public institution (or distinct part thereof) for persons with intellectual or developmental disability or related conditions.
4. Hospice care (in accordance with § 1905(o) of the Act).
5. Any other medical care and any type of remedial care recognized under state law, specified by the U.S. Secretary of Health and Human Services: care and services provided in religious nonmedical health care institutions, nursing facility services for patients younger than 21 years of age, or emergency hospital services.
6. Private health insurance premiums, coinsurance, and deductibles when cost effective (pursuant to P.L. No. 101-508 § 4402).
7. Program of All-Inclusive Care for the Elderly (PACE) services are provided for eligible individuals as an optional State Plan service for categorically needy individuals without limitation.
8. Pursuant to P.L. No. 111-148 § 4107, counseling and pharmacotherapy for cessation of tobacco use by pregnant women shall be covered.
  - a. Counseling and pharmacotherapy for cessation of tobacco use by pregnant women means diagnostic, therapy, and counseling services and pharmacotherapy (including the coverage of prescription and nonprescription tobacco cessation agents approved by the U.S. Food and Drug Administration) for cessation of tobacco use by pregnant women who use tobacco products or who are being treated for tobacco use that is furnished (i) by or under the supervision of a physician, (ii) by any other health care professional who is legally authorized to provide tobacco cessation services under state law and is authorized to provide Medicaid coverable services other than tobacco cessation services, or (iii) by any other health care professional who is legally authorized to provide tobacco cessation services under state law and who is specifically designated by the U.S. Secretary of Health and Human Services in federal regulations for this purpose.

b. No cost sharing shall be applied to these services. In addition to other services that are covered for pregnant women, 12VAC30-50-510 also provides for other smoking cessation services that are covered for pregnant women.

9. Inpatient psychiatric facility services and residential psychiatric treatment services (including therapeutic group homes and psychiatric residential treatment facilities) for individuals younger than 21 years of age.

10. Coverage of routine patient cost for items and services as defined in 1905(gg) of the Social Security Act that are furnished in connection with participation in a qualifying clinical trial.

12VAC30-50-60 Services provided to all medically needy groups without limitations  
Services as described in Part III (12VAC30-50-100 et seq.) of this chapter are provided to all medically needy groups without limitations.

1. Nursing facility services (other than services in an institution for mental diseases) for individuals 21 years of age or older.

2. Early and periodic screening and diagnosis of individuals younger than 21 years of age, and treatment of conditions found.

3. Pursuant to P.L. No. 111-148 § 4107, counseling and pharmacotherapy for cessation of tobacco use by pregnant women shall be covered.

a. Counseling and pharmacotherapy for cessation of tobacco use by pregnant women means diagnostic, therapy, and counseling services and pharmacotherapy (including the coverage of prescription and nonprescription tobacco cessation agents approved by the U.S. Food and Drug Administration) for cessation of tobacco use by pregnant women who use tobacco products or who are being treated for tobacco use that is furnished (i) by or under the supervision of a physician, (ii) by any other health care professional who is legally authorized to provide tobacco cessation services under state law and is authorized to provide Medicaid coverable services other than tobacco cessation services, or (iii) by any other health care professional who is legally authorized to provide tobacco cessation services under state law and who is specifically designated by the U.S. Secretary of Health and Human Services in federal regulations for this purpose.

b. No cost sharing shall be applied to these services. In addition to other services that are covered for pregnant women, 12VAC30-50-510 also provides for other smoking cessation services that are covered for pregnant women.

4. Intermediate care facility services (other than such services in an institution for mental diseases) for persons determined in accordance with § 1905(a)(4)(A) of the Social Security Act (the Act) to be in need of such care.

5. Hospice care (in accordance with § 1905(o) of the Act).

6. Any other medical care or any other type of remedial care recognized under state law, specified by the U.S. Secretary of Health and Human Services, including: care and services provided in religious nonmedical health care institutions, skilled nursing facility services for patients younger than 21 years of age, and emergency hospital services.

7. Private health insurance premiums, coinsurance and deductibles when cost effective (pursuant to P.L. No. 101-508 § 4402).

8. Program of All-Inclusive Care for the Elderly (PACE) services are provided for eligible individuals as an optional State Plan service for medically needy individuals without limitation.

9. Inpatient psychiatric facility services and residential psychiatric treatment services (including therapeutic group homes and psychiatric residential treatment facilities) for individuals younger than 21 years of age.

10. Coverage of routine patient cost for items and services as defined in 1905(gg) of the Social Security Act that are furnished in connection with participation in a qualifying clinical trial.