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TO: **EMILY MCCLELLAN**
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FROM: **MICHELLE A. L'HOMMEDIEU**
Assistant Attorney General

DATE: **May 9, 2017**

SUBJECT: **Final/Exempt Regulations – Revision for CMS Conditions of Participation (4792/7893)**

I have reviewed the attached exempt final regulations regarding the update of citations to an amended federal regulation related to Conditions of Participation for Home Health Agencies. 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 Centers for Medicare & Medicaid Services of the U.S. Department of Health & Human Services ("CMS") published a final rule in the *Federal Register* (FR 82:4504) on January 13, 2017, which becomes effective July 13, 2017. Among the federal regulatory changes is the replacement of regulations concerning home health aide services, that is, replacing 42 CFR § 484.36 with 42 CFR § 484.80. *See id.* at 4514.

Based on my review, it is my view that the Director of DMAS, acting on behalf of the Board of Medical Assistance Services, pursuant to 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 not amend the State Plan, and approval by CMS is therefore unnecessary. If you have any questions, please contact me at 786-6005.

cc: Kim F. Piner, Esq.

Attachment

Project 5056 - Final

DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

Revision for CMS Conditions of Participation

12VAC30-50-160. Home health services.

A. Service must be ordered or prescribed and directed or performed within the scope of a license of a practitioner of the healing arts. Home health services shall be provided in accordance with guidelines found in the Virginia Medicaid Home Health Manual.

B. Nursing services provided by a home health agency.

1. Intermittent or part-time nursing service provided by a home health agency or by a registered nurse when no home health agency exists in the area.

2. Patients may receive up to five visits by a licensed nurse annually. Limits are per recipient, regardless of the number of providers rendering services. Annually shall be defined as July 1 through June 30 for each recipient. If services beyond these limitations are determined by the physician to be required, then the provider shall request prior authorization from DMAS for additional services. Payment shall not be made for additional service unless authorized by DMAS.

C. Home health aide services provided by a home health agency.

1. Home health aides must function under the supervision of a registered nurse.

2. Home health aides must meet the certification requirements specified in 42 CFR 484.~~36~~80.

3. For home health aide services, patients may receive up to 32 visits annually. Limits shall be per recipient, regardless of the number of providers rendering services. Annually shall be defined as July 1 through June 30 for each recipient.

D. Physical therapy, occupational therapy, or speech pathology services and audiology services provided by a home health agency or medical rehabilitation facility.

1. Service covered only as part of a physician's plan of care.

2. Patients may receive up to five visits for each rehabilitative therapy service ordered annually without authorization. Limits shall apply per recipient regardless of the number of providers rendering services. Annually shall be defined as July 1 through June 30 for each recipient. If services beyond these limitations are determined by the physician to be required, then the provider shall request prior authorization from DMAS for additional services.

E. The following services are not covered under the home health services program:

1. Medical social services;

2. Services or items which would not be paid for if provided to an inpatient of a hospital, such as private-duty nursing services, or items of comfort which have no medical necessity, such as television;

3. Community food service delivery arrangements;

4. Domestic or housekeeping services which are unrelated to patient care and which materially increase the time spent on a visit;

5. Custodial care which is patient care that primarily requires protective services rather than definitive medical and skilled nursing care; and

6. Services related to cosmetic surgery.

12VAC30-60-70. Utilization control: Home health services.

A. Home health services which meet the standards prescribed for participation under Title XVIII, excluding any homebound standard, will be supplied.

B. Home health services shall be provided by a home health agency that is licensed by the Virginia Department of Health (VDH); or that is certified by the VDH under provisions of Title XVIII (Medicare) or Title XIX (Medicaid) of the Social Security Act; or that is accredited either by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or by the Community Health Accreditation Program (CHAP) established by the National League of Nursing. Services shall be provided on a part-time or intermittent basis to a recipient in his place of residence. The place of residence shall not include a hospital or nursing facility. Home health services must be prescribed by a physician and be part of a written plan of care that the physician shall review at least every 60 days.

C. Covered services. Any one of the following services may be offered as the sole home health service and shall not be contingent upon the provision of another service.

1. Nursing services;

2. Home health aide services;

3. Physical therapy services;

4. Occupational therapy services; or

5. Speech-language pathology services.

D. General conditions. The following general conditions apply to skilled nursing, home health aide, physical therapy, occupational therapy, and speech-language pathology services provided by home health agencies.

1. The patient must be under the care of a physician who is legally authorized to practice and who is acting within the scope of his license. The physician may be the patient's private physician or a physician on the staff of the home health agency or a physician working under an arrangement with the institution which is the patient's residence or, if the agency is hospital-based, a physician on the hospital or agency staff.

2. When a patient is admitted to home health services a start-of-care comprehensive assessment must be completed no later than five calendar days after the start of care date.

3. Services shall be furnished under a written plan of care and must be established and periodically reviewed by a physician. The requested services or items must be necessary to carry out the plan of care and must be related to the patient's condition. The initial plan of care (certification) must be reviewed by the attending physician, or physician designee. The physician must sign the initial certification before the home health agency may bill DMAS.

4. A physician shall review and recertify the plan of care every 60 days. A physician recertification shall be performed within the last five days of each current 60-day certification period, i.e., between and including days 56-60. The physician recertification statement must indicate the continuing need for services and should estimate how long home health services will be needed. The physician must sign the recertification before the home health agency may bill DMAS.

5. The physician-orders for therapy services shall include the specific procedures and modalities to be used, identify the specific discipline to carry out the plan of care, and indicate the frequency and duration for services.

6. A written physician's statement located in the medical record must certify that:

a. The patient needs licensed nursing care, home health aide services, physical or occupational therapy, or speech-language pathology services;

b. A plan for furnishing such services to the individual has been established and is periodically reviewed by a physician; and

c. These services were furnished while the individual was under the care of a physician.

7. The plan of care shall contain at least the following information:

a. Diagnosis and prognosis;

b. Functional limitations;

c. Orders for nursing or other therapeutic services;

d. Orders for home health aide services, when applicable;

e. Orders for medications and treatments, when applicable;

f. Orders for special dietary or nutritional needs, when applicable; and

g. Orders for medical tests, when applicable, including laboratory tests and x-rays.

E. Utilization review shall be performed by DMAS to determine if services are appropriately provided and to ensure that the services provided to Medicaid recipients are medically necessary and appropriate. Such post payment review audits may be unannounced. Services not specifically documented in patients' medical records as having been rendered shall be deemed not to have been rendered and no reimbursement shall be provided.

F. All services furnished by a home health agency, whether provided directly by the agency or under arrangements with others, must be performed by appropriately qualified personnel. The following criteria shall apply to the provision of home health services:

1. Nursing services. Nursing services must be provided by a registered nurse or by a licensed practical nurse under the supervision of a graduate of an approved school of professional nursing and who is licensed as a registered nurse.

2. Home health aide services. Home health aides must meet the qualifications specified for home health aides by 42 CFR 484.~~36~~80. Home health aide services may include assisting with personal hygiene, meal preparation and feeding, walking, and taking and recording blood pressure, pulse, and respiration. Home health aide services must be provided under the general supervision of a registered nurse. A recipient may not receive duplicative home health aide and personal care aide services.

3. Rehabilitation services. Services shall be specific and provide effective treatment for patients' conditions in accordance with accepted standards of medical practice. The amount, frequency, and duration of the services shall be reasonable. Rehabilitative services shall be provided with the expectation, based on the assessment made by physicians of patients' rehabilitation potential, that the condition of patients will improve significantly in a reasonable and generally predictable period of time, or shall be necessary to the establishment of a safe and effective maintenance program required in connection with the specific diagnosis.

a. Physical therapy services shall be directly and specifically related to an active written plan of care approved by a physician after any needed consultation with a physical therapist licensed by the Board of Physical Therapy. The services shall be of a level of complexity and sophistication, or the condition of the patient shall be of a nature that the services can only be performed by a physical therapist licensed by the Board of Physical Therapy, or a physical therapy assistant who is licensed by the Board of Physical Therapy and is under the direct supervision of a physical therapist licensed by the Board of Physical Therapy. When physical therapy services are

provided by a qualified physical therapy assistant, such services shall be provided under the supervision of a qualified physical therapist who makes an onsite supervisory visit at least once every 30 days. This supervisory visit shall not be reimbursable.

b. Occupational therapy services shall be directly and specifically related to an active written plan of care approved by a physician after any needed consultation with an occupational therapist registered and licensed by the National Board for Certification in Occupational Therapy and licensed by the Virginia Board of Medicine. The services shall be of a level of complexity and sophistication, or the condition of the patient shall be of a nature that the services can only be performed by an occupational therapist registered and licensed by the National Board for Certification in Occupational Therapy and licensed by the Virginia Board of Medicine, or an occupational therapy assistant who is certified by the National Board for Certification in Occupational Therapy under the direct supervision of an occupational therapist as defined above. When occupational therapy services are provided by a qualified occupational therapy assistant, such services shall be provided under the supervision of a qualified occupational therapist, as defined above, who makes an onsite supervisory visit at least once every 30 days. This supervisory visit shall not be reimbursable.

c. Speech-language pathology services shall be directly and specifically related to an active written plan of care approved by a physician after any needed consultation with a speech-language pathologist licensed by the Virginia Department of Health Professions, Virginia Board of Audiology and Speech-Language Pathology. The services shall be of a level of complexity and sophistication, or the condition of the patient shall be of a nature that the services can only be performed by a speech-

language pathologist licensed by the Virginia Department of Health Professions, Virginia Board of Audiology and Speech-Language Pathology.

4. A visit shall be defined as the duration of time that a nurse, home health aide, or rehabilitation therapist is with a client to provide services prescribed by a physician and that are covered home health services. Visits shall not be defined in measurements or increments of time.

12VAC30-60-130. Hospice services.

A. Admission criteria.

1. Service election. To be eligible for hospice coverage under Medicare or Medicaid, the recipient shall be "terminally ill," defined as having a life expectancy of six months or less, and except for individuals under 21 years of age, elect to receive hospice services rather than active treatment for the illness. Both the attending physician (if the individual has an attending physician) and the hospice medical director, or the attending physician and the physician member of the interdisciplinary team, must initially certify the life expectancy. The election statement shall include (i) identification of the hospice that will provide care to the individual; (ii) the individual's or representative's acknowledgement that he has been given a full understanding of the palliative rather than curative nature of hospice care as it relates to the individual's terminal illness; (iii) with the exception of children, defined as persons younger than 21 years of age, acknowledgement that certain Medicaid services are waived by the election; (iv) the effective date of the election; and (v) the signature of the individual or representative.

2. Service revocation. The recipient shall have the right to revoke his election of hospice services at any time during the covered hospice periods. DMAS shall be contacted if the recipient revokes his hospices services. If the recipient reelects the hospice services, the

hospice periods will begin as an initial time frame. Therefore, the above certification and time requirements will apply. The recipient cannot retroactively receive hospice benefits from previously unused hospice periods. The recipient's written revocation statement shall be maintained in the recipient's medical record.

B. General conditions. The general conditions provided in this subsection apply to nursing care, medical social services, physician services, counseling services, short-term inpatient care, durable medical equipment and supplies, drugs and biologicals, home health aide and homemaker services, and rehabilitation services.

The recipient shall be under the care of a physician who is legally authorized to practice and who is acting within the scope of his license. The hospice medical director or the physician member of the interdisciplinary team shall be a licensed doctor of medicine or osteopathy. Hospice services may be provided in the recipient's home or in a freestanding hospice, hospital or nursing facility.

The hospice shall obtain the written certification that an individual is terminally ill in accordance with the following procedures:

1. For the initial 90-day benefit period of hospice coverage, a Medicaid written certification (DMAS 420) shall be signed and dated by the medical director of the hospice and the attending physician, or the physician member of the hospice interdisciplinary team and the attending physician, at the beginning of the certification period. This initial certification shall be submitted for preauthorization within 14 days from the physician's signature date. This certification shall be maintained in the recipient's medical record.

2. For the subsequent 90-day hospice period, a Medicaid written certification (DMAS 420) shall be signed and dated before or on the begin date of the 90-day hospice period

by the medical director of the hospice or the physician member of the hospice's interdisciplinary team. The certification shall include the statement that the recipient's medical prognosis is that his life expectancy is six months or less. This certification of continued need for hospice services shall be maintained in the recipient's medical record.

3. After the second 90-day hospice period and until the recipient is no longer in the Medicaid hospice program, a Medicaid written certification shall be signed and dated every 60 days on or before the begin date of the 60-day period. This certification statement shall be signed and dated by the medical director of the hospice or the physician member of the hospice's interdisciplinary team. The certification shall include the statement that the recipient's medical prognosis is that his life expectancy is six months or less. This certification shall be maintained in the recipient's medical record.

C. Utilization review. Authorization for hospice services requires an initial preauthorization by DMAS and physician certification of life expectancy. Utilization review will be conducted to determine if services were provided by the appropriate provider and to ensure that the services provided to Medicaid recipients are medically necessary and appropriate. Services not specifically documented in the recipients' medical records as having been rendered shall be deemed not to have been rendered and no coverage shall be provided. All hospice services shall be provided in accordance with guidelines established in the Virginia Medicaid Hospice Manual.

D. Hospice services are a medically directed, interdisciplinary program of palliative services for terminally ill people and their families, emphasizing pain and symptom control. The rules pertaining to them are:

1. Interdisciplinary team. An interdisciplinary team shall include at least the following individuals: a physician (either a hospice employee or a contract physician), a registered

nurse, a social worker, and a pastoral or other counselor. Other professionals may also be members of the interdisciplinary team depending on the terminally ill recipient's medical needs.

2. Nursing care. Nursing care shall be provided by a registered nurse or by a licensed practical nurse under the supervision of a graduate of an approved school of professional nursing and who is licensed as a registered nurse.

3. Medical social services. Medical social services shall be provided by a social worker who has at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education, and who is working under the direction of a physician.

4. Physician services. Physician services shall be performed by a professional who is licensed to practice, who is acting within the scope of his license, and who is a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor. The hospice medical director or the physician member of the interdisciplinary team shall be a licensed doctor of medicine or osteopathy.

5. Counseling services. Counseling services shall be provided to the terminally ill individual and the family members or other persons caring for the individual at home. Counseling, including dietary counseling, may be provided both for the purpose of training the individual's family or other caregiver to provide care, and for the purpose of helping the individual and those caring for him to adjust to the individual's approaching death. Bereavement counseling consists of counseling services provided to the individual's family up to one year after the individual's death. Bereavement counseling is a required hospice service, but it is not reimbursable.

6. Short-term inpatient care. Short-term inpatient care may be provided in a participating hospice inpatient unit, or a participating hospital or nursing facility. General inpatient care may be required for procedures necessary for pain control or acute or chronic symptom management which cannot be provided in other settings. Inpatient care may also be furnished to provide respite for the individual's family or other persons caring for the individual at home.

7. Durable medical equipment and supplies. Durable medical equipment as well as other self-help and personal comfort items related to the palliation or management of the patient's terminal illness is covered. Medical supplies include those that are part of the written plan of care.

8. Drugs and biologicals. Only drugs which are used primarily for the relief of pain and symptom control related to the individual's terminal illness are covered.

9. Home health aide and homemaker services. Home health aides providing services to hospice recipients shall meet the qualifications specified for home health aides by 42 CFR ~~484.36~~484.80. Home health aides may provide personal care services. Aides may also perform household services to maintain a safe and sanitary environment in areas of the home used by the patient, such as changing the bed or light cleaning and laundering essential to the comfort and cleanliness of the patient. Homemaker services may include assistance in personal care, maintenance of a safe and healthy environment and services to enable the individual to carry out the plan of care. Home health aide and homemaker services shall be provided under the general supervision of a registered nurse.

10. Rehabilitation services. Rehabilitation services include physical and occupational therapies and speech-language pathology services that are used for purposes of

symptom control or to enable the individual to maintain activities of daily living and basic functional skills.

a. Occupational therapy services shall be those services furnished a patient which meet all of the following conditions:

(1) The services shall be directly and specifically related to an active written treatment plan designed by the physician after any needed consultation with an occupational therapist registered and certified by the American Occupational Therapy Certification Board;

(2) The services shall be of a level of complexity and sophistication, or the condition of the patient shall be of a nature, that the services can only be performed by an occupational therapist registered and certified by the American Occupational Therapy Certification Board or an occupational therapy assistant certified by the American Occupational Therapy Certification Board under the direct supervision of an occupational therapist as defined above; and

(3) The services shall be specific and provide effective treatment for the patient's condition in accordance with accepted standards of medical practice, including the requirement that the amount, frequency, and duration of the services shall be reasonable.

b. Physical therapy services shall be those furnished a patient which meet all of the following conditions:

(1) The services shall be directly and specifically related to an active written treatment plan designed by a physician after any needed consultation with a physical therapist licensed by the Board of Medicine;

(2) The services shall be of a level of complexity and sophistication, or the condition of the patient shall be of a nature, that the services can only be performed by a physical therapist licensed by the Board of Medicine, or a physical therapy assistant who is licensed by the Board of Medicine and under the direct supervision of a physical therapist licensed by the Board of Medicine; and

(3) The services shall be specific and provide effective treatment for the patient's condition in accordance with accepted standards of medical practice, including the requirement that the amount, frequency, and duration of the services shall be reasonable.

c. Speech-language pathology services shall be those services furnished a patient which meet all of the following conditions:

(1) The services shall be directly and specifically related to an active written treatment plan designed by a physician after any needed consultation with a speech-language pathologist licensed by the Board of Audiology and Speech-Language Pathology;

(2) The services shall be of a level of complexity and sophistication, or the condition of the patient shall be of a nature, that the services can only be performed by a speech-language pathologist licensed by the Board of Audiology and Speech-Language Pathology; and

(3) The services shall be specific and provide effective treatment for the patient's condition in accordance with accepted standards of medical practice, including the requirement that the amount, frequency, and duration of the services shall be reasonable.

11. Documentation of hospice services shall be maintained in the recipient's medical record. Coordination of patient care between all health care professionals should be maintained in the recipient's medical record.