Title of Rule: Revision to the Medical Assistance Act Rule concerning Nursing Facility Immunization Administration.
Rule Number: MSB 20-12-30-A
Division / Contact / Phone: Health Program Office / Whitney McOwen/303-866-4441 / Christina Winship/303-866-5578 / Richard Clark/303-866-6518

STATEMENT OF BASIS AND PURPOSE

1. Summary of the basis and purpose for the rule or rule change. (State what the rule says or does and explain why the rule or rule change is necessary).

   This rule revision will allow the Department to reimburse pharmacies for administration of the COVID-19 vaccine in Long-term Care Facilities through the Centers for Disease Control and Prevention's (CDC's) Pharmacy Partnership for Long-term Care Program or other partnership between an LTC and a pharmacy.

2. An emergency rule-making is imperatively necessary

   ☐ to comply with state or federal law or federal regulation and/or
   ☒ for the preservation of public health, safety and welfare.

   Explain:

   These revisions are required to facilitate administration of the forthcoming COVID-19 vaccine to nursing home facility residents.

3. Federal authority for the Rule, if any:

   Section 6008(b)(4) of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), P.L. 116-136

4. State Authority for the Rule:

   Sections 25.5-1-301 through 25.5-1-303, C.R.S. (2020);

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REGULATORY ANALYSIS

1. Describe the classes of persons who will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.

   Health First Colorado members residing in nursing facilities and pharmacy providers licensed to administer vaccines will benefit from the flexibility provided by this rule revision. Current policy limits reimbursement to vaccines ordered by the resident's own physician and administration is either included in the facility's rate or part of a regularly scheduled home health service.

2. To the extent practicable, describe the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

   This revision will help expedite administration of the COVID-19 vaccine to Health First Colorado members residing in nursing facilities. The rule will also allow nursing facility providers to utilize existing partnerships with pharmacies to administer the vaccine.

3. Discuss the probable costs to the Department and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

   The Department expects this change to cost approximately $60,000 in total funds, which will be incorporated through the regular budget process.

4. Compare the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

   The proposed rule will facilitate the expeditious administration of the COVID-19 vaccine to this population.

5. Determine whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

   There are no less costly or intrusive methods to achieve the purpose of the proposed rule.

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6. Describe any alternative methods for achieving the purpose for the proposed rule that were seriously considered by the Department and the reasons why they were rejected in favor of the proposed rule.

   There are no alternative methods for achieving the purpose of the proposed rule.

8.815 IMMUNIZATION SERVICES

8.815.1 Definitions

8.815.1.A. Advisory Committee on Immunization Practices (ACIP) means the group of medical and public health experts that develops recommendations on how to use vaccines to control diseases in the United States. ACIP was established under Section 222 of the Public Health Service Act (42 U.S.C. § 2l7a).

8.815.1.B. Immunization means the process whereby a person is made immune or resistant to an infectious disease, typically by the administration of a vaccine.

8.815.1.C. School District means any board of cooperative services established pursuant to article 5 of title 22, C.R.S., any state educational institution that serves students in kindergarten through twelfth grade including, but not limited to, the Colorado School for the Deaf and Blind, created in article 80 of title 22, C.R.S., and any public School District organized under the laws of Colorado except a junior college district.

8.815.1.D. Vaccine means a biological preparation that improves immunity to a particular disease.

8.815.1.E. Vaccine Administration Services means the provision of an injection, nasal absorption, or oral administration of a vaccine product.

8.815.1.F. Vaccines for Children (VFC) means the federally funded program administered through the Centers for Disease Control for the purchase and distribution of pediatric vaccines to program-registered providers for the Immunization of vaccine-eligible children 18 years of age and younger.

8.815.2 Client Eligibility

8.815.2.A. All Colorado Medicaid clients are eligible for Immunization and Vaccine Administration Services.

8.815.3 Provider Eligibility

8.815.3.A. Rendering Providers

1. Colorado Medicaid enrolled providers are eligible to administer Vaccines and Vaccine Administration Services as follows:

    a. If it is within the scope of the provider's practice;

    b. In accordance with the requirements at 10 CCR 2505-10, Section 8.200.2.; and

    c. If the provider is administering Vaccines and Vaccine Administration Services to a client 18 years of age or younger, the provider is using Vaccines provided free of cost by the federal government, including through the VFC program.

8.815.3.B. Prescribing Providers

1. Colorado Medicaid enrolled providers are eligible to prescribe Vaccines and Vaccine Administration Services in accordance with Section 8.815.3.A.1.a.-b.

8.815.4 Covered Services

8.815.4.A. Vaccines identified in the ACIP Vaccine Recommendations and Guidelines are updated routinely and are covered as follows:

1. For clients 18 years of age and younger, Vaccines are either provided through the VFC program or are otherwise provided without cost by the federal government.

2. For clients 19 years of age and older, Vaccines are covered by Colorado Medicaid.

8.815.4.B. Administration of Vaccines identified in the ACIP Vaccine Recommendations and Guidelines is a covered service for all clients.

8.815.4.C. Immunization and Vaccine Administration Services that are provided by home health agencies, physicians, or other non-physician practitioners to clients at nursing facilities, group homes, or residential treatment centers are covered only as follows:

1. Immunization services for clients who are residents of nursing facilities and clients receiving home health services are covered only if ordered by their physician. The skilled nursing component for Immunization administration provided at a nursing facility is included in the facility's rate or part of a regularly scheduled home health service for clients receiving home health services.

   a. Administration of the COVID-19 vaccine will be reimbursed as specified at 10 CCR 2505-10, Section 8.443.7.A.5.a.

2. Clients who are residents of an Alternative Care Facility, as defined at Section 8.495.1, may receive Immunization services from their own physician. They may also receive Immunization services as part of a home health service in accordance with Section 8.815.4.C.1.

8.815.5 Prior Authorization Requirements

8.815.5.A. Prior authorization is not required for this benefit.

8.815.6 Non-covered Services

8.815.6.A. The following services are not covered by Colorado Medicaid:

1. For clients 18 years of age and younger, Vaccines that have been obtained from a source other than the federal government;

2. Immunization and Vaccine Administration Services provided by a School District provider; and

3. Travel-related Immunization and Vaccine Administration Services.

8.443 NURSING FACILITY REIMBURSEMENT

8.443.7 HEALTH CARE REIMBURSEMENT RATE CALCULATION

8.443.7.A Health Care Services Defined: Health Care Services means the categories of reasonable, necessary and patient-related support services listed below. No service shall be considered a health care service unless it is listed below:

1. The salaries, payroll taxes, worker compensation payments, training and other employee benefits of registered nurses, licensed practical nurses, restorative aides, nurse aides, feeding assistants, registered dietician, MDS coordinators, nursing staff development personnel, nursing administration (not clerical) case manager, patient care coordinator, quality improvement, clinical director. These personnel shall be appropriately licensed and/or certified, although nurse aides may work in any facility for up to four months before becoming certified.

   If a facility employee or a management company/home office employee or owner has dual health care and administrative duties, the provider must keep contemporaneous time records or perform time studies to verify hours worked performing health care related duties. If no contemporaneous time records are kept or time studies performed, total salaries, payroll taxes and benefits of personnel performing health care and administrative functions will be classified as administrative and general. Licenses are not required unless otherwise specified. Periodic time studies in lieu of contemporaneous time records may be used for the allocation. Time studies used must meet the following criteria:

   a. A minimally acceptable time study must encompass at least one full week per month of the cost reporting period.

   b. Each week selected must be a full work week (Monday to Friday, Monday to Saturday, or Sunday to Saturday).

   c. The weeks selected must be equally distributed among the months in the cost reporting period, e.g., for a 12 month period, 3 of the 12 weeks in the study must be the first week beginning in the month, 3 weeks the 2nd week beginning in the month, 3 weeks the 3rd, and 3 weeks the fourth.

   d. No two consecutive months may use the same week for the study, e.g., if the second week beginning in April is the study week for April, the weeks selected for March and May may not be the second week beginning in those months.

   e. The time study must be contemporaneous with the costs to be allocated. Thus, a time study conducted in the current cost reporting year may not be used to allocate the costs of prior or subsequent cost reporting years.

f. The time study must be provider specific. Thus, chain organizations may not use a time study from one provider to allocate the costs of another provider or a time study of a sample group of providers to allocate the costs of all providers within the chain.

2. The salaries, payroll taxes, workers compensation payments, training and other employee benefits of medical records librarians, social workers, central or medical supplies personnel and activity personnel.

Health Information Managers (Medical Records Librarians): Must work directly with the maintenance and organization of medical records.

Social Workers: Includes social workers, life enhancement specialists and admissions coordinators.

Central or Medical Supply personnel: Includes duties associated with stocking and ordering medical and/or central supplies.

Activity personnel: Personnel classified as "activities" must have a direct relationship (i.e., providing entertainment, games, and social opportunities) to residents. For instance, security guards and hall monitors do not qualify as activities personnel. Costs associated with security guards and hall monitors are classified as administrative and general.

3. If the provider's chart of accounts directly identifies payroll taxes and benefits associated with health care versus administrative and general cost centers, the amounts directly identified will be appropriately allowed as either health care or administrative and general. If these costs are comingled in the chart of accounts, payroll taxes and benefits shall be allocated to the cost centers (health care and administrative and general) based on total employee wages reported in those cost centers. The reporting method for payroll taxes and benefits by cost center is required to be consistent from year to year. When a provider wishes to change its reporting method because it believes the change will result in more appropriate and a more accurate allocation, the provider must make a written request to the Department for approval of the change ninety (90) days prior to the end of that cost reporting period. The Department has sixty (60) days from receipt of the request to make a decision or the change is automatically accepted. The provider must include with the request all supporting documentation to establish that the new method is more accurate. If the Department approves the provider's request, the change must be applied to the cost reporting period for which the request was made and to all subsequent cost reporting periods. The approval will be for a minimum three year period. The provider cannot change methods until the three year period has expired.

4. Personnel licensed to perform patient care duties shall be reported in the administrative and general cost center if the duties performed by these personnel are administrative in nature.

5. Non-prescription drugs ordered by a physician that are included in the per diem rate, including costs associated with vaccinations.

a. Pharmacies are eligible for reimbursement for administration of the COVID-19 vaccine.

6. Consultant fees for nursing, medical records, registered dieticians, patient activities, social workers, pharmacies, physicians and therapies. Consultants shall be appropriately licensed and/or certified, as applicable and professionally qualified in the field for which

they are consulting. The guidance provided in (1) above for employees also applies to consultants.

7. Purchases, rental, depreciation, interest and repair expenses of health care equipment and medical supplies used for health care services such as nursing care, medical records, social services, therapies and activities. Purchases, lease expenses or fees associated with computers and software (including the associated training and upgrades) used in departments within the facility that provide direct or indirect health care services to residents. Dual purpose software that includes both a health care and administrative and general component will be considered a health care service.

8. Purchase or rental of motor vehicles and related expenses, including salary and benefits associated with the van driver(s), for operating or maintaining the vehicles to the extent that they are used to transport residents to activities or medical appointments. Such use shall be documented by contemporaneous logs if there is dual purpose. An example of the dual purpose vehicle is one used for both resident transport and maintenance activities.

9. Copier lease expense.

10. Salaries, fees, or other expenses related to health care duties performed by a facility owner or manager who has a medical or nursing credential. Note that costs associated with the Nursing Home Administrator are an administrative and general cost.

11. Related Party Management Fees and Home Office Costs

Related party management fees and home office costs shall be classified as administrative and general. However, costs incurred by the facility as a direct charge from the related party which are listed in this section, may be included in the health care cost center equal to the actual costs incurred by the related party. Documentation supporting the cost and health care licenses must be maintained. Only salaries, payroll taxes and employee benefits associated with health care personnel will be considered as allowable in the health care cost center. No overhead expenses will be included. The amount allowable in the health care cost category will be calculated in one of two ways:

a. Keeping contemporaneous time logs in 15 minute increments supporting the number of hours worked at each facility.

b. Distributing the cost evenly across all facilities as follows: the amount allowable in each health care facility's health care costs shall be equal to the total salary, payroll taxes and benefits of the health care personnel divided by the number of facilities where the health care personnel worked during the year. For example, if a nurse's total salary, payroll taxes, and benefits total $80,000, and the nurse worked on five facilities during the year, $16,000 is allowable in each of the facility's health care costs.

Auditable documentation supporting the number of facilities worked on during the year must be maintained. Even if a related party exception is granted in accordance with 10 CCR 2505-10 section 8.441.5.I.4, no mark-up or profit will be allowed in the health care cost center, only supported actual costs.

Non-Related Party Management Fees

Non-related party management fees shall be classified as administrative and general. However, costs incurred by the facility as a direct charge from the management company which are listed in this section, may be included in the health care cost center. Management contracts which specify percentages related to health care services will not be considered a direct charge from the management company.

12. Professional liability insurance, whether self-insurance or purchased, loss settlements, claims paid and insurance deductibles.

13. Medical director fees.

14. Therapies and services provided by an individual qualified to provide these services under Federal Medicare/Medicaid regulations including:

Utilization review
Dental care, when required by federal law
Audiology
Psychology and mental health services
Physical therapy
Recreational therapy
Occupational therapy
Speech therapy

15. Nursing licenses and permits, disposal costs associated with infectious material (medical or hazardous waste), background checks and flu or hepatitis shots and uniforms for personnel listed in (1) above.

16. Food Costs. Food costs means the cost of raw food, and shall not include the costs of property, staff, preparation or other items related to the food program.

8.443.7.B CLASS I HEALTH CARE STATE-WIDE MAXIMUM ALLOWABLE PER DIEM REIMBURSEMENT RATES (LIMIT)

For the purpose of reimbursing Medicaid-certified nursing facility providers a per diem rate for direct and indirect health care services and raw food, the state department shall establish an annual maximum allowable rate (limit). In computing the health care per diem limit, each nursing facility provider shall annually submit cost reports, and actual days of care shall be counted, not occupancy-imputed days of care. The health care limit will be calculated as follows:

1. Determination of the health care limit beginning on July 1 each year shall utilize the most current MED-13 cost report filed, in accordance with these regulations, by each facility on or before December 31 of the preceding year.

2. The MED-13 cost report shall be deemed filed if actually received by the Department's designee or postmarked by the U.S. Postal Service on or before December 31.

3. If, in the judgment of the Department, the MED-13 contains errors, whether willful or accidental, that would impair the accurate calculation of the limit, the Department may:

a. Exclude part, or all, of a provider's MED-13.

b. Replace part, or all, of a provider's MED-13 with the MED-13 the provider submitted in its most recent audited cost report adjusted by the percentage change in the Skilled Nursing Facility Market Basket (without capital) published

by Global Insight, Inc. measured from the midpoint of the reporting period to the midpoint of the payment-setting period.

4. The health care limit and the data used in that computation shall be subject to administrative appeal only on or before the expiration of the thirty (30) day period following the date the information is made available.

5. The health care limit shall not exceed one hundred twenty-five percent (125%) of the median costs of direct and indirect health care services and raw food as determined by an array of all class I facility providers; except that, for state veteran nursing homes, the health care limit will be one hundred thirty percent (130%) of the median cost.

a. In determining the median cost, the cost of direct health care shall be case-mix neutral.

b. Actual days of care shall be counted, not occupancy-imputed days of care, for purposes of calculating the health care limit.

c. Amounts contained in cost reports used to determine the health care limit shall be adjusted by the percentage change in the Skilled Nursing Facility Market Basket (without capital) inflation indexes published by Global Insight, Inc. measured from the midpoint of the reporting period of each cost report to the midpoint of the payment-setting period.

i). The percentage change shall be rounded at least to the fifth decimal point.

ii). The latest available publication prior to July 1 rate setting shall be used to determine the inflation indexes.

6. Annually, the state department shall redetermine the median per diem cost based upon the most recent cost reports filed during the period ending December 31 of the prior year.

7. The health care limit for health care reimbursement shall be changed effective July 1 of each year and individual facility rates shall be adjusted accordingly.

8.443.7.C. CLASS I HEALTH CARE PER DIEM LIMITATION ON HEALTH CARE GROWTH

For the fiscal year beginning July 1, 2009, and for each fiscal year thereafter, any increase in the direct and indirect health care services and raw food costs shall not exceed eight percent (8%) per year. The calculation of the eight percent per year limitation for rates effective on July 1, 2009, shall be based on the direct and indirect health care services and raw food costs in the as-filed facility's cost reports up to and including June 30, 2009. For the purposes of calculating the eight percent limitation for rates effective after July 1, 2009, the limitation shall be determined and indexed from the direct and indirect health care services and raw food costs as reported and audited for the rates effective July 1, 2009.

8.443.7.D. CLASS I HEALTH CARE PER DIEM REIMBURSEMENT RATES AND MEDICAID CASE MIX INDEX (CMI):

For the purpose of reimbursing a Medicaid-certified class I nursing facility provider a per diem rate for the cost of direct and indirect health care services and raw food, the State Department shall establish an annually readjusted schedule to pay each nursing facility provider the actual amount of the costs. This payment shall not exceed the health care limit described at 10 CCR

2505-10 section 8.443.7B. The health care per diem reimbursement rate is the lesser of the provider's acuity adjusted health care limit or the provider's acuity adjusted actual allowable health care costs.

The state department shall adjust the per diem rate to the nursing facility provider for the cost of direct health care services based upon the acuity or case-mix of the nursing facility provider's residents in order to adjust for the resource utilization of its residents. The state department shall determine this adjustment in accordance with each resident's status as identified and reported by the nursing facility provider on its federal Medicare and Medicaid minimum data set assessment. The state department shall establish a case-mix index for each nursing facility provider according to the resource utilization groups system, using only nursing weights. The state department shall calculate nursing weights based upon standard nursing time studies and weighted by facility population distribution and Colorado-specific nursing salary ratios. The state department shall determine an average case-mix index for each nursing facility provider's Medicaid residents on a quarterly basis

1. Acuity information used in the calculation of the health care reimbursement rate shall be determined as follows:

    a. A facility's cost report period resident acuity case mix index shall be the average of quarterly resident acuity case mix indices, carried to four decimal places, using the facility wide resident acuity case mix indices. The quarters used in this average shall be the quarters that most closely coincide with the cost reporting period.

    b. The facility's Medicaid resident acuity case mix index shall be a two quarter average, carried to four decimal places, of the Medicaid resident acuity average case mix indices. The two quarter average used in the July 1 rate calculation shall be the same two quarter average used in the rate calculation for the rate effective date prior to July 1.

    c. The statewide average case mix index shall be a simple average, carried to four decimal places, of the cost report period case mix indices for all Medicaid facilities calculated effective each July 1.

    d. The normalization ratio shall be determined by dividing the statewide average case mix index by the facility's cost report period case mix index.

    e. The facility Medicaid acuity ratio shall be determined by dividing the facility's Medicaid resident acuity case mix index by the facility cost report period case mix index.

    f. The facility overall resident acuity ratio shall be determined by dividing the facility cost report period case mix index by the statewide average case mix acuity index.

2. The annual facility specific direct health care maximum reimbursement rate shall be determined as follows:

    a. The percentage of the normalized per diem case mix adjusted nursing cost to total health care cost shall be determined by dividing the normalized per diem

case mix adjusted nursing cost by the sum of the normalized per diem case mix adjusted nursing cost and other health care per diem cost.

b. The statewide health care maximum allowable reimbursement rate (calculated at 10 CCR 2505-10 section 8.443.7B) shall be multiplied by the percentage established in the preceding paragraph to determine the amount of the statewide health care maximum allowable reimbursement rate that is attributable to the case mix reimbursement rate component.

c. The facility specific maximum reimbursement rate for case mix adjusted nursing costs shall be determined by multiplying the facility specific overall acuity ratio by the amount of the statewide health care maximum allowable reimbursement rate that is attributable to the case mix reimbursement rate component as established in the preceding paragraph.

3. The annual facility specific indirect health care maximum allowable reimbursement shall be determined as follows:

a. The percentage of the indirect health care per diem cost to total health care cost shall be determined by dividing the indirect health care per diem cost by the sum of the normalized per diem case mix adjusted nursing cost and other health care per diem cost.

b. The facility specific in direct health care maximum reimbursement rate shall be determined by multiplying the statewide health care maximum allowable reimbursement rate by the percentage established in the preceding paragraph.

4. The case mix reimbursement rate component shall be determined as follows:

a. The case mix reimbursement rate component shall be established using the facility Medicaid resident acuity ratio.

b. This ratio shall be multiplied by the lesser of the facility's allowable case mix adjusted nursing cost or the facility specific maximum reimbursement rate for case mix adjusted nursing costs. The resulting calculation shall the case mix reimbursement rate component.

5. The indirect health care reimbursement rate shall be the lesser of the facility's allowable other health care cost or the facility specific other health care maximum reimbursement rate.

8.443.7.E DETERMINATION OF THE HEALTH CARE SERVICES MAXIMUM ALLOWABLE RATE (LIMIT) FOR CLASS II AND IV FACILITIES

1. For class II facilities, one hundred twenty-five percent (125%) of the median actual costs of all class II facilities;

2. For non-state administered class IV facilities, one hundred twenty-five percent (125%) of the median actual costs of all class IV facilities.

3. State-administered class IV facilities shall not be subject to the health care limit. The Med-13s of the state-administered class IV facilities shall be included in the health care limit calculation for other class IV facilities.

4. The determination of the reasonable cost of services shall be made every 12 months.

5. Determination of the health care limit beginning on July 1 each year shall utilize the most current MED-13 cost report filed in accordance with these regulations, by each facility on or before May 2.

6. The MED-13 cost report shall be deemed submitted if actually received by the Department's designee or postmarked by the U.S. Postal Service on or before May 2nd.

7. If, in the judgment of the Department, the MED-13 contains errors, whether willful or accidental, that would impair the accurate calculation of reasonable costs for the class, the Department may:

   a. Exclude part, or all, of a provider's MED-13; or

   b. Replace part, or all, of a provider's MED-13 with the MED-13 the provider submitted in its most recent audited cost report adjusted by the change in the "medical care" component of the Consumer Price Index published for all urban consumers (CPI-U) by the United States Department of Labor, Bureau of Labor Statistics over the time period from the provider's most recent audited cost report.

8. State-administered class IV facilities shall not be subject to the maximum reasonable rate ceiling. The Med-13s of the state-administered class IV facilities shall be included in the maximum rate calculation for other class IV facilities.

9. The maximum reasonable rate and the data used in that computation shall be subject to administrative appeal only on or before the expiration of the thirty (30) day period following the date the information is made available.

10. The maximum rate for reimbursement shall be changed effective July 1 of each year and individual facility rates shall be adjusted accordingly.