

Dear Senators HEIDER, Souza, Jordan, and
Representatives WOOD, Packer, Chew:

The Legislative Services Office, Research and Legislation, has received the enclosed rules of
the Department of Health and Welfare:

IDAPA 16.03.09 - Medicaid Basic Plan Benefits - Proposed Rule (Docket No. 16-0309-1601);

IDAPA 16.03.09 - Medicaid Basic Plan Benefits - Proposed Rule (Docket No. 16-0309-1602).

Pursuant to Section 67-454, Idaho Code, a meeting on the enclosed rules may be called by the
cochairmen or by two (2) or more members of the subcommittee giving oral or written notice to Research
and Legislation no later than fourteen (14) days after receipt of the rules' analysis from Legislative
Services. The final date to call a meeting on the enclosed rules is no later than 12/29/2016. If a meeting is
called, the subcommittee must hold the meeting within forty-two (42) days of receipt of the rules' analysis
from Legislative Services. The final date to hold a meeting on the enclosed rules is 01/27/2017.

The germane joint subcommittee may request a statement of economic impact with respect to a
proposed rule by notifying Research and Legislation. There is no time limit on requesting this statement,
and it may be requested whether or not a meeting on the proposed rule is called or after a meeting has
been held.

To notify Research and Legislation, call 334-4834, or send a written request to the address on the
memorandum attached below.



Eric Milstead
Director

Legislative Services Office

Idaho State Legislature

Serving Idaho's Citizen Legislature

MEMORANDUM

TO: Rules Review Subcommittee of the Senate Health & Welfare Committee and the House Health & Welfare Committee

FROM: Senior Legislative Research Analyst - Elizabeth Bowen

DATE: December 12, 2016

SUBJECT: Department of Health and Welfare

IDAPA 16.03.09 - Medicaid Basic Plan Benefits - Proposed Rule (Docket No. 16-0309-1601)

IDAPA 16.03.09 - Medicaid Basic Plan Benefits - Proposed Rule (Docket No. 16-0309-1602)

The Department of Health and Welfare submits notice of proposed rulemaking at IDAPA 16.03.09.

The first rule revises requirements relating to home health services and durable medical equipment and is intended to align this chapter of rules with recent changes in federal regulations. Negotiated rulemaking was not conducted due to the nature of the rule change. There is no anticipated negative fiscal impact on the state general fund. The Department states that this rulemaking is authorized pursuant to several sections of the Idaho Code, including sections 56-202, 56-253, and 56-264, which specifically authorize rulemaking.

The second rule clarifies pricing methodologies for Medicaid provider reimbursement. The rule also revises some language to align with federal regulations. Negotiated rulemaking was not conducted due to the nature of the rule change. There is no anticipated negative fiscal impact on the state general fund. The Department states that this rulemaking is authorized pursuant to several sections of the Idaho Code, including sections 56-202, 56-253, and 56-264, which specifically authorize rulemaking.

cc: Department of Health and Welfare
Tamara Prisock

IDAPA 16 - DEPARTMENT OF HEALTH AND WELFARE

16.03.09 - MEDICAID BASIC PLAN BENEFITS

DOCKET NO. 16-0309-1601

NOTICE OF RULEMAKING - PROPOSED RULE

AUTHORITY: In compliance with Section 67-5221(1), Idaho Code, notice is hereby given that this agency has initiated proposed rulemaking procedures. The action is authorized pursuant to Sections 56-202, 56-203, 56-250 through 56-257, and 56-260 through 56-266, Idaho Code; also 42 CFR 440.70.

PUBLIC HEARING SCHEDULE: The public hearings concerning this rulemaking will be held as follows:

Monday, October 17, 2016 2:30 pm (Local)	Tuesday, October 18, 2016 11:30 am (Local)	Wednesday, October 19, 2016 9:00 am (Local)
Medicaid Reg. VII Office 150 Shoup Avenue Large Conf. Rm., 2nd Floor Idaho Falls, ID	Medicaid Reg. I Office 1120 Ironwood Drive, Ste. 102 Coeur d'Alene, ID	Medicaid Central Office 3232 W. Elder Street Conf. Rm. D - West/East Boise, ID
TELECONFERENCE CALL-IN		

Toll Free: 1-877-820-7831 -- Participant Code: 701700

The hearing site will be accessible to persons with disabilities. Requests for accommodation must be made not later than five (5) days prior to the hearing, to the agency address below.

DESCRIPTIVE SUMMARY: The following is a nontechnical explanation of the substance and purpose of the proposed rulemaking:

These rule changes serve to better ensure program integrity, to increase quality of care, and to align the chapter with recent changes regarding home health services and durable medical equipment (DME) in federal regulations.

These rule changes will:

1. Clarify requirements for physician orders for home health services and DME;
2. Add a requirement for a documented face-to-face encounter prior to delivery of services or equipment and supplies for home health services and DME providers;
3. Clarify the non-physician practitioners who may conduct face-to-face encounters; and
4. Clarify that home health services and DME cannot be restricted to services provided in the home, and that they may be provided in any setting in which normal life activities take place.

FEE SUMMARY: The following is a specific description of the fee or charge imposed or increased: N/A

FISCAL IMPACT: The following is a specific description, if applicable, of any negative fiscal impact on the state general fund greater than ten thousand dollars (\$10,000) during the fiscal year as a result of this rulemaking:

This rulemaking has no fiscal impact to the state general fund or any other funds. This rulemaking is intended to be cost-neutral.

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220(2), Idaho Code, negotiated rulemaking was not conducted and was deemed not feasible as these changes bring the rules into alignment with federal regulations and preserve federal participation dollars for these programs.

INCORPORATION BY REFERENCE: Pursuant to Section 67-5229(2)(a), Idaho Code, the edition of the CMS/Medicare Durable Medical Equipment Coverage Manual incorporated by reference in this chapter is being updated from 2007 edition to the 2016 edition along with the URL to the most current edition.

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Karen Westbrook at (208) 364-1960.

Anyone may submit written comments regarding this proposed rulemaking. All written comments must be directed to the undersigned and must be delivered on or before October 26, 2016.

DATED this 30th day of August, 2016.

Tamara Prisock
DHW - Administrative Rules Unit
450 W. State Street - 10th Floor
P.O. Box 83720
Boise, ID 83720-0036
Phone: (208) 334-5500 / Fax: (208) 334-6558
E-mail: dhwrules@dhw.idaho.gov

THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 16-0309-1601
(Only Those Sections With Amendments Are Shown.)

004. INCORPORATION BY REFERENCE.

The following are incorporated by reference in this chapter of rules: (3-30-07)

~~01. 42 CFR Part 447. 42 CFR Part 447, "Payment for Services," revised as of October 1, 2001, is available from CMS, 7500 Security Blvd, Baltimore, M.D., 21244 1850 or on the Code of Federal Regulations internet site at http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfr/browse/Title42/42cfr447_main_02.tpl. (3-30-07)~~

~~02. American Academy of Pediatrics (AAP) Periodicity Schedule. This document is available on the internet at https://www.aap.org/en-us/Documents/periodicity_schedule.pdf. The schedule is also available at the Division of Medicaid, 3232 Elder Street, Boise, ID 83705. (3-30-07)~~

031. American Speech-Language-Hearing Association (ASHA): Medicaid Guidance for Speech-Language Pathology Services. The American Speech-Language-Hearing Association (2004) Medicaid Guidance for Speech-Language Pathology Services: Addressing the "Under the Direction of" Rule technical report is available on the internet at: <http://www.asha.org/policy/ps2004-00098.htm>. The report may also be obtained at the ASHA National Office, 2200 Research Boulevard, Rockville, MD 20850-3289, telephone (301) 296-5700. (3-29-10)

~~04. CDC Child and Teen BMI Calculator. The Centers for Disease Control (CDC) Child and Teen Body Mass Index (BMI) Calculator is available on the internet at <http://www.cdc.gov/nccdphp/dnpa/bmi/index.htm>. The Calculator is also available through the Division of Medicaid, 3232 Elder Street, Boise, ID 83705. (3-30-07)~~

052. DSM-5. American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, (DSM-5) Arlington, VA, American Psychiatric Association, 2013. A copy of the manual is available for public review at the Department of Health and Welfare, 450 West State Street, Boise, Idaho, 83702. (3-20-14)

~~063.~~ **Estimated Useful Lives of Depreciable Hospital Assets, 2004 Revised Edition, Guidelines Lives.** This document may be obtained from American Hospital Publishing, Inc., 211 East Chicago Avenue, Chicago, IL, 60611. (3-30-07)

~~07.~~ **Idaho Infant Toddler Program Implementation Manual (Revised September 1999).** The full text of the "Idaho Infant Toddler Program Implementation Manual," revised September 1999, is available at <http://www.infanttoddler.idaho.gov>. (7-1-13)

~~08.~~ **Idaho Special Education Manual, September 2001.** The full text of the "Idaho Special Education Manual, September 2001" is available on the Internet at [http://www.sde.idaho.gov/sped/shared/2016 Special Education Manual.pdf](http://www.sde.idaho.gov/sped/shared/2016%20Special%20Education%20Manual.pdf). A copy is also available at the Idaho Department of Education, 650 West State Street, P.O. Box 83720, Boise, Idaho 83720-0027. (3-30-07)

~~094.~~ **Medicare Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) Jurisdiction D Supplier Manual 200716, As Amended (CMS/Medicare DME Coverage Manual).** Since the supplier manual is amended on a quarterly basis by CMS, the current year's manual is being incorporated by reference, as amended, to allow for the incorporation of the most recent amendments to the manual. The full text of the Medicare: CMS/Medicare DME MAC Jurisdiction D Supplier Coverage Manual is available via the Internet at <https://med.noridianmedicare.com/web/jddme/education/supplier-manual>. (3-30-07)()

~~10.~~ **Physician's Current Procedural Terminology (CPT® Manual).** This document may be obtained from the American Medical Association, P.O. Box 10950, Chicago, Illinois 60610, or online at <http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt.page>. (3-30-07)

~~105.~~ **Provider Reimbursement Manual (PRM).** The Provider Reimbursement Manual (PRM), Part I and Part II (CMS Publication 15-1 and 15-2), is available on the CMS website at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals.html>. (3-30-07)

~~1206.~~ **SIB-R Comprehensive Manual.** Scales of Independent Behavior - Revised Comprehensive Manual, 1996, Riverside Publishing Co, 425 Spring Lake Drive, Itasca, IL 60143-2079. A copy is available for public review at the Department of Health and Welfare, 450 West State Street, Boise, Idaho 83702. (3-30-07)

~~1307.~~ **Travel Policies and Procedures of the Idaho State Board of Examiners.** The text of "Idaho State Travel Policies and Procedures of the Idaho State Board of Examiners," Appendices A and B, June 13, 2000, is available at the Office of the State Controller, 700 W. State St., 5th Fl., Box 83720, Boise, Idaho 83720-0011 or on the Internet at <http://www.sco.idaho.gov>. (3-30-07)

(BREAK IN CONTINUITY OF SECTIONS)

010. DEFINITIONS: A THROUGH H.

For the purposes of these rules, the following terms are used as defined below: (3-30-07)

01. AABD. Aid to the Aged, Blind, and Disabled. (3-30-07)

02. Abortion. The medical procedure necessary for the termination of pregnancy endangering the life of the woman, or the result of rape or incest, or determined to be medically necessary in order to save the health of the woman. (3-30-07)

03. Amortization. The systematic recognition of the declining utility value of certain assets, usually not owned by the organization or intangible in nature. (3-30-07)

04. Ambulatory Surgical Center (ASC). Any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization, and which is certified by the U.S. Department

- of Health and Human Services as an ASC. (3-30-07)
- 05. Audit.** An examination of provider records on the basis of which an opinion is expressed representing the compliance of a provider's financial statements and records with Medicaid law, regulations, and rules. (3-30-07)
- 06. Auditor.** The individual or entity designated by the Department to conduct the audit of a provider's records. (3-30-07)
- 07. Audit Reports.** (3-30-07)
- a.** Draft Audit Report. A preliminary report of the audit finding sent to the provider for the provider's review and comments. (3-30-07)
- b.** Final Audit Report. A final written report containing the results, findings, and recommendations, if any, from the audit of the provider, as approved by the Department. (3-30-07)
- c.** Interim Final Audit Report. A written report containing the results, findings, and recommendations, if any, from the audit of the provider, sent to the Department by the auditor. (3-30-07)
- 08. Bad Debts.** Amounts due to provider as a result of services rendered, but which are considered uncollectible. (3-30-07)
- 09. Basic Plan.** The medical assistance benefits included under this chapter of rules. (3-30-07)
- 10. Buy-In Coverage.** The amount the State pays for Part B of Title XVIII of the Social Security Act on behalf of the participant. (3-30-07)
- 11. Certified Registered Nurse Anesthetist (CRNA).** A Registered Nurse qualified by advanced training in an accredited program in the specialty of nurse anesthesia to manage the care of the patient during the administration of anesthesia in selected surgical situations. (3-30-07)
- 12. Claim.** An itemized bill for services rendered to one (1) participant by a provider and submitted to the Department for payment. (3-30-07)
- 13. CFR.** Code of Federal Regulations. (3-30-07)
- 14. Clinical Nurse Specialist (CNS).** A licensed professional nurse who meets all the applicable requirements to practice as clinical nurse specialist under Title 54, Chapter 14, Idaho Code, and IDAPA 23.01.01, "Rules of the Idaho Board of Nursing." (~~3-30-07~~) ()
- 15. CMS.** Centers for Medicare and Medicaid Services. (3-30-07)
- 16. CMS/Medicare DME Coverage Manual. Medicare Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) Jurisdiction D Supplier Manual.** ()
- 167. Co-Payment.** The amount a participant is required to pay to the provider for specified services. (3-30-07)
- 178. Cost Report.** A fiscal year report of provider costs required by the Medicare program and any supplemental schedules required by the Department. (3-30-07)
- 189. Customary Charges.** Customary charges are the rates charged to Medicare participants and to patients liable for such charges, as reflected in the facility's records. Those charges are adjusted downward, when the provider does not impose such charges on most patients liable for payment on a charge basis or, when the provider fails to make reasonable collection efforts. The reasonable effort to collect such charges is the same effort necessary for Medicare reimbursement as is needed for unrecovered costs attributable to certain bad debt as described in

Chapter 3, Sections 310 and 312, PRM. (3-30-07)

~~19~~**20.** **Department.** The Idaho Department of Health and Welfare or a person authorized to act on behalf of the Department. (3-30-07)

~~20~~**1.** **Director.** The Director of the Idaho Department of Health and Welfare or his designee. (3-30-07)

~~21~~**2.** **Dual Eligibles.** Medicaid participants who are also eligible for Medicare. (3-30-07)

~~22~~**3.** **Durable Medical Equipment (DME).** Equipment ~~other than prosthetics or orthotics that can withstand repeated use by one (1) or more individuals, is~~ and appliances that: ()

a. Are primarily and customarily used to serve a medical purpose; ()

b. Are generally not useful to an ~~person~~ individual in the absence of a ~~disability,~~ illness, or injury, ~~is appropriate for use in the home, and is;~~ ()

c. Can withstand repeated use; ()

d. Can be reusable or removable; ()

e. Are suitable for use in any setting in which normal life activities take place; and ()

f. Are reasonable and medically necessary for the treatment of a ~~disability,~~ illness, or injury for a Medicaid participant. (~~5-8-09~~)()

~~23~~**4.** **Emergency Medical Condition.** A medical condition manifesting itself by acute symptoms of sufficient severity, including severe pain, that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in the following: (3-30-07)

a. Placing the health of the individual, or, with respect to a pregnant woman, the health of the woman or unborn child, in serious jeopardy. (3-30-07)

b. Serious impairment to bodily functions. (3-30-07)

c. Serious dysfunction of any bodily organ or part. (3-30-07)

~~24~~**5.** **EPSDT.** Early and Periodic Screening, Diagnosis, and Treatment. (3-30-07)

~~25~~**6.** **Facility.** Facility refers to a hospital, nursing facility, or intermediate care facility for people with intellectual disabilities. (3-30-07)

~~26~~**7.** **Federally Qualified Health Center (FQHC).** An entity that meets the requirements of 42 U.S.C Section 1395x(aa)(4). The FQHC may be located in either a rural or urban area designated as a shortage area or in an area that has a medically underserved population. (3-30-07)

~~27~~**8.** **Fiscal Year.** An accounting period that consists of twelve (12) consecutive months. (3-30-07)

~~28~~**9.** **Forced Sale.** A forced sale is a sale required by a bankruptcy, foreclosure, the provisions of a will or estate settlement pursuant to the death of an owner, physical or mental incapacity of an owner that requires ownership transfer to an existing partner or partners, or a sale required by the ruling of a federal agency or by a court order. (3-30-07)

~~29~~**30.** **Healthy Connections.** The primary care case management model of managed care under Idaho Medicaid. (3-30-07)

- ~~301.~~ **Home Health Services.** Services and items that are: ()
- ~~a.~~ Ordered by a physician ~~and~~ as part of a home health plan of care; ()
 - ~~b.~~ Performed by a licensed ~~nurse, registered physical therapist, or home health aide as defined in IDAPA 16.03.07, "Rules for Home Health Agencies."~~ qualified professional; (3-30-07)()
 - ~~c.~~ Typically received by a Medicaid participant at the participant's place of residence; and ()
 - ~~d.~~ Reasonable and medically necessary for the treatment of a disability, illness, or injury for a Medicaid participant. ()
- ~~312.~~ **Hospital.** A hospital as defined in Section 39-1301, Idaho Code. (3-30-07)
- ~~323.~~ **Hospital-Based Facility.** A nursing facility that is owned, managed, or operated by, or is otherwise a part of a licensed hospital. (3-30-07)
- 011. DEFINITIONS: I THROUGH O.**
For the purposes of these rules, the following terms are used as defined below: (3-30-07)
- 01. ICF/ID.** Intermediate Care Facility for People with Intellectual Disabilities. An ICF/ID is an entity licensed as an ICF/ID and federally certified to provide care to Medicaid and Medicare participants with developmental disabilities. (3-30-07)
- 02. Idaho Behavioral Health Plan (IBHP).** The Idaho Behavioral Health Plan is a prepaid ambulatory health plan (PAHP) that provides outpatient behavioral health coverage for Medicaid-eligible children and adults. Outpatient behavioral health services include mental health and substance use disorder treatment as well as case management services. The coordination and provision of behavioral health services as authorized through the IBHP contract are provided to qualified, enrolled participants by a statewide network of professionally licensed and certified behavioral health providers. (3-20-14)
- 03. Idaho Infant Toddler Program.** The Idaho Infant Toddler Program serves children from birth up to three (3) years of age (36 months), and must meet the requirements and provisions of the Individuals with Disabilities Education Act (IDEA), Part C; the Family Education Rights and Privacy Act; Sections 16-101, et seq., Idaho Code, regarding early intervention services; and the Idaho State Plan for Early Intervention Services under IDEA, Part C. (7-1-13)
- a.** These requirements for the Idaho Infant Toddler Program include: (7-1-13)
 - i. Adherence to procedural safeguards and time lines; (7-1-13)
 - ii. Use of multi-disciplinary assessments and Individualized Family Service Plans (IFSPs); (7-1-13)
 - iii. Provision of early intervention services in the natural environment; (7-1-13)
 - iv. Transition planning; and (7-1-13)
 - v. Program enrollment and reporting requirements. (7-1-13)
 - b.** The Idaho Infant Toddler Program may provide the following services for Medicaid reimbursement: (7-1-13)
 - i. Occupational therapy; (7-1-13)
 - ii. Physical therapy; (7-1-13)
 - iii. Speech-language pathology; (7-1-13)

- iv. Audiology; and (7-1-13)
- v. Children's developmental disabilities services defined under IDAPA 16.03.10, "Medicaid Enhanced Plan Benefits." (7-1-13)
- 04. In-Patient Hospital Services.** Services that are ordinarily furnished in a hospital for the care and treatment of an in-patient under the direction of a physician or dentist except for those services provided in mental hospitals. (3-30-07)
- 05. Intermediary.** Any organization that administers Title XIX or Title XXI; in this case the Department of Health and Welfare. (3-30-07)
- 06. Intermediate Care Facility Services.** Those services furnished in an intermediate care facility as defined in 42 CFR 440.150, but excluding services provided in a Christian Science Sanatorium. (3-30-07)
- 07. Legal Representative.** A parent with custody of a minor child, one who holds a legally-executed and effective power of attorney for health decisions, or a court-appointed guardian whose powers include the power to make health care decisions. (3-30-07)
- 08. Legend Drug.** A drug that requires, by federal regulation or state rule, the order of a licensed medical practitioner before dispensing or administration to the patient. (3-30-07)
- 09. Level of Care.** The classification in which a participant is placed, based on severity of need for institutional care. (3-30-07)
- 10. Licensed, Qualified Professionals.** Individuals licensed, registered, or certified by national certification standards in their respective discipline, or otherwise qualified within the state of Idaho. (3-30-07)
- 11. Lock-In Program.** An administrative sanction, required of a participant found to have misused the services provided by the Medical Assistance Program. The participant is required to select one (1) provider in the identified area(s) of misuse to serve as the primary provider. (3-30-07)
- 12. Locum Tenens/Reciprocal Billing.** The practice of a physician to retain a substitute physician when the regular physician is absent for reasons such as illness, pregnancy, vacation, or continuing medical education. The substitute physician is called the "Locum Tenens" physician. Reimbursement to a Locum Tenens physician will be limited to a period of ninety (90) continuous days. Reciprocal billing occurs when a substitute physician covers the regular physician during an absence or on an on-call basis a period of fourteen (14) continuous days or less. (3-30-07)
- 13. Medical Assistance.** Payments for part or all of the cost of services funded by Titles XIX or XXI of the federal Social Security Act, as amended. (3-30-07)
- 14. Medicaid.** Idaho's Medical Assistance Program. (3-30-07)
- 15. Medicaid-Related Ancillary Costs.** For the purpose of these rules, those services considered to be ancillary by Medicare cost reporting principles. Medicaid-related ancillary costs will be determined by apportioning direct and indirect costs associated with each ancillary service to Medicaid participants by dividing Medicaid charges into total charges for that service. The resulting percentage, when multiplied by the ancillary service cost, will be considered Medicaid-related ancillaries. (3-30-07)
- 16. Medical Necessity (Medically Necessary).** A service is medically necessary if: (3-30-07)
- a. It is reasonably calculated to prevent, diagnose, or treat conditions in the participant that endanger life, cause pain, or cause functionally significant deformity or malfunction; and (3-30-07)
- b. There is no other equally effective course of treatment available or suitable for the participant

requesting the service which is more conservative or substantially less costly. (3-30-07)

c. Medical services must be of a quality that meets professionally-recognized standards of health care and must be substantiated by records including evidence of such medical necessity and quality. Those records must be made available to the Department upon request. (3-30-07)

17. Medical Supplies. ~~Items excluding drugs, biologicals, and equipment furnished incident to a physician's professional services commonly furnished in a physician's office or items ordered by a physician for the treatment of a specific medical condition. These items are generally not useful to an individual in the absence of an illness and are consumable, nonreusable, disposable, and generally have no salvage value. Surgical dressings, ace bandages, splints and casts, and other devices used for reduction of fractures or dislocations are considered supplies. Healthcare-related items that are consumable, disposable, or cannot withstand repeated use by more than one (1) individual, are suitable for use in any setting in which normal life activities take place, and are reasonable and medically necessary for the treatment of a disability, illness, or injury for a Medicaid participant.~~ (3-30-07)()

18. Medicare Durable Medical Equipment Medicare Administrative Contractor Jurisdiction D Supplier Manual (CMS/Medicare DME Coverage Manual). A publication that is incorporated by reference in Section 004 of these rules and contains information on DME supplier enrollment, documentation, claim submission, coverage, appeals, and overpayments. ()

189. Midwife. An individual qualified as one of the following: (3-29-12)

a. Licensed Midwife. A person who is licensed by the Idaho Board of Midwifery under Title 54, Chapter 55, Idaho Code, and IDAPA 24.26.01, "Rules of the Idaho Board of Midwifery." (3-29-12)

b. Nurse Midwife (NM). An advanced practice professional nurse who is licensed by the Idaho Board of nursing and who meets all the applicable requirements to practice as a nurse midwife under Title 54, Chapter 14, Idaho Code, and IDAPA 23.01.01, "Rules of the Idaho Board of Nursing." (3-29-12)

1920. Nominal Charges. A public provider's charges are nominal where aggregate charges amount to less than one-half (1/2) of the reasonable cost of the services provided. (3-30-07)

201. Nonambulatory. Unable to walk without assistance. (3-30-07)

212. Non-Legend Drug. Any drug the distribution of which is not subject to the ordering, dispensing, or administering by a licensed medical practitioner. (3-30-07)

223. Nurse Practitioner (NP). A registered nurse or licensed professional nurse (RN) who meets all the applicable requirements to practice as nurse practitioner under Title 54, Chapter 14, Idaho Code, and IDAPA 23.01.01, "Rules of the Idaho Board of Nursing." (7-1-13)

234. Nursing Facility (NF). An institution, or distinct part of an institution, that is primarily engaged in providing skilled nursing care and related services for participants. It is an entity licensed as a nursing facility and federally certified to provide care to Medicaid and Medicare participants. Participants must require medical or nursing care, or rehabilitation services for injuries, disabilities, or sickness. (3-30-07)

245. Orthotic. Pertaining to or promoting the support of an impaired joint or limb. (3-30-07)

256. Outpatient Hospital Services. Preventive, diagnostic, therapeutic, rehabilitative, or palliative items or services furnished by or under the direction of a physician or dentist to a patient not in need of inpatient hospital care. (3-30-07)

267. Out-of-State Care. Medical service that is not provided in Idaho or bordering counties is considered out-of-state. Bordering counties outside Idaho are considered out-of-state for the purpose of authorizing long term care. (3-30-07)

278. Oxygen-Related Equipment. Equipment which is utilized or acquired for the routine

administration of oxygen in ~~the home~~ any setting in which normal life activities take place. This includes oxygen tanks, regulators, humidification nebulizers, oxygen concentrators, and related equipment. Equipment which is used solely for the administration of medication into the lungs is excluded from this definition. ~~(3-30-07)~~()

(BREAK IN CONTINUITY OF SECTIONS)

200. PROVIDER APPLICATION PROCESS.

01. Provider Application. Providers who meet Medicaid enrollment requirements may apply for Idaho Medicaid provider status with the Department. All healthcare providers who are eligible for a National Provider Identifier (NPI) must apply using that identifying number. For providers not eligible for a NPI, the Department will assign a provider number upon approval of the application. (3-20-14)

02. Screening Levels. In accordance with 42 CFR 455.450, the Department will assign risk levels of “limited,” “moderate,” or “high” to defined groups of providers. These assignments and definitions will be published in the provider handbook. (3-20-14)

03. Medicare Enrollment Requirement for Specified Providers. The following providers must enroll as Medicare providers or demonstrate enrollment with another state’s Medicaid agency prior to enrollment or revalidation as an Idaho Medicaid provider. ~~(3-20-14)~~()

a. Any providers classified in the “moderate” or “high” categorical risk level, as defined in the provider handbook. (3-20-14)

b. Any provider type classified as an institutional provider by Medicare. (3-20-14)

04. Disclosure of Information by Providers and Fiscal Agents. All enrolling providers and their fiscal agents must comply with the disclosure requirements as stated in 42 CFR 455, Subpart B, “Disclosure of Information by Providers and Fiscal Agents.” (3-20-14)

05. Denial of Provider Agreement. The Department may deny provider status by refusing a request to enter into a provider agreement, refusing to extend an existing agreement, or refusing to enter into additional agreements with any individual or entity. Reasons for denying provider status include those described in IDAPA 16.05.07, “The Investigation and Enforcement of Fraud, Abuse, and Misconduct,” Section 265. (3-20-14)

06. Mandatory Denial of Provider Agreement. The Department will deny a request for a provider agreement when: (3-20-14)

a. The provider fails to meet the qualifications required by rule or by any applicable licensing board; (3-20-14)

b. The provider was a managing employee, or had an ownership interest, as defined in 42 CFR Section 455.101, in any entity that was previously found by the Department to have engaged in fraudulent conduct, or abusive conduct related to the Medicaid program, or has demonstrated an inability to comply with the requirements related to the provider status for which application is made, including submitting false claims or violating provisions of any provider agreement; (3-20-14)

c. The provider was a managing employee, or had an ownership interest, as defined in 42 CFR Section 455.101, in any entity that failed to repay the Department for any overpayments, or to repay claims previously found by the Department to have been paid improperly, whether the failure resulted from refusal, bankruptcy, or otherwise, unless prohibited by law; (3-20-14)

d. The provider employs as a managing employee, contracts for any management services, shares any ownership interests, or would be considered a related party to any individual or entity identified in Subsections 200.06.a. through 200.06.c. of this rule. (3-20-14)

- e. The provider fails to comply with any applicable requirement under 42 CFR 455. (3-20-14)
- f. The provider is precluded from enrollment due to a temporary moratorium issued by the Secretary of Health and Human Services in accordance with 42 CFR 455.470. (3-20-14)
- g. The provider is currently suspended from Medicare or Medicaid in any state, or has been terminated from Medicare or Medicaid in any state. (3-20-14)

(BREAK IN CONTINUITY OF SECTIONS)

455. AMBULATORY SURGICAL CENTER SERVICES: PROVIDER REIMBURSEMENT.

01. Payment Methodology. ASC services reimbursement is designed to pay for use of facilities and supplies necessary to safely care for the patient. Such services are reimbursed as follows: (3-30-07)

a. ASC service payments represent reimbursement for the costs of goods and services recognized by the Medicare program as described in 42 CFR, Part 416. Payment levels will be determined by the Department. Any surgical procedure covered by the Department, but which is not covered by Medicare will have a reimbursement rate established by the Department. (3-30-07)

b. ASC services include the following: (3-30-07)

i. Nursing, technician, and related services; (3-30-07)

ii. Use of ASC facilities; (3-30-07)

iii. Drugs, biologicals, surgical dressings, supplies, splints, casts, and appliances and equipment directly related to the provision of surgical procedures; (3-30-07)

iv. Diagnostic or therapeutic services or items directly related to the provision of a surgical procedure; (3-30-07)

v. Administration, record-keeping and housekeeping items and services; and (3-30-07)

vi. Materials for anesthesia. (3-30-07)

c. ASC services do not include the following services: (3-30-07)

i. Physician services; (3-30-07)

ii. Laboratory services, x-ray or diagnostic procedures (other than those directly related to the performance of the surgical procedure); (3-30-07)

iii. Prosthetic and orthotic devices; (3-30-07)

iv. Ambulance services; (3-30-07)

v. Durable medical equipment for use in the patient's home typically used in the participant's place of residence, but may be suitable for use in any setting in which normal life activities take place, other than a hospital, nursing facility, or ICF/ID; and ~~(3-30-07)~~()

vi. Any other service not specified in Subsection 455.01.b. of this rule. (3-30-07)

02. Payment for Ambulatory Surgical Center Services. Payment is made at a rate established in

accordance with Section 230 of these rules.

(3-30-07)

(BREAK IN CONTINUITY OF SECTIONS)

522. MIDDLELEVEL PRACTITIONER SERVICES: COVERAGE AND LIMITATIONS.

The Medicaid Program will pay for services provided by certified registered nurse anesthetists (CRNA), nurse practitioners (NP), nurse midwives (NM), clinical nurse specialists (CNS), and physician assistants (PA), as defined in Sections 010, 011, 012 of these rules and in accordance with the provisions found under Sections 523 through 525 of these rules. (3-30-07)()

523. (RESERVED)

524. MIDDLELEVEL PRACTITIONER SERVICES: PROVIDER QUALIFICATIONS AND DUTIES.

01. Identification of Services. The required services must be covered under the legal scope of practice as identified by the appropriate State rules of the CRNA, NP, NM, CNS, or PA. (3-30-07)()

02. Deliverance of Services. The services must be delivered under physician supervision, if required by Idaho Statute. (3-30-07)

525. MIDDLELEVEL PRACTITIONER SERVICES: PROVIDER REIMBURSEMENT.

01. Billing of Services. Billing for the services must be as provided by the CRNA, NP, NM, CNS, or PA, and not represented as a physician service. (3-30-07)()

02. Payments Made Directly to CRNA. Payments under the fee schedule must be made directly to the CRNA under the individual provider number assigned to the CRNA. Rural hospitals that qualify for a Medicare exception and employ or contract CRNAs may be reimbursed on a reasonable cost basis. (3-30-07)

03. Reimbursement Limits. The Department will reimburse for each service to be delivered by the NP, NM, CNS, or PA as either the billed charge or reimbursement limit established by the Department, whichever is less. (3-30-07)()

(BREAK IN CONTINUITY OF SECTIONS)

720. HOME HEALTH SERVICES: DEFINITIONS.

~~Home health services encompass services ordered by the participant's attending physician as a part of a plan of care, that include nursing services, home health aide, physical therapy, occupational therapy, and speech-language pathology services.~~ (4-2-08)

01. Home Health Plan of Care. A written description of home health services to be provided to a participant. ()

02. Home Health Services. Home health services are services and items, including nursing services, home health aide services, physical therapy, occupational therapy, speech-language pathology services, audiology services, and medical supplies, equipment, and appliances that are: ()

a. Ordered by a physician as part of a home health plan of care; ()

b. Performed by a licensed, qualified professional acting within their authorized scope of practice; ()

c. Typically received by a participant at the participant's place of residence, but may be received in

any setting in which normal life activities take place, other than a hospital, nursing facility, ICF/ID (unless such services are not otherwise required to be provided by the ICF/ID), or any other setting in which payment is made, or could be made, under Medicaid for inpatient services that include room and board; and ()

d. Reasonable and medically necessary for the treatment of a disability, illness, or injury for a Medicaid participant. ()

03. Place of Residence. For the purposes of home health services, generally any setting in which a participant makes their home, other than a hospital, nursing facility, or ICF/ID. ()

(BREAK IN CONTINUITY OF SECTIONS)

723. HOME HEALTH SERVICES: PROCEDURAL REQUIREMENTS.

01. Physician Orders. ()

a. Home health services must be ordered by a physician. Such orders must include at a minimum, the physician's National Provider Identifier (NPI), the services or items to be provided, the frequency, and, where applicable, the expected duration of time for which the home health services will be needed. ()

b. In the event that home health services are required for extended periods, these services must be reordered as necessary, but at least every sixty (60) days for services and at least annually for medical supplies, equipment, and appliances. ()

02. Face-to-Face Encounter for Home Health Services -- Excluding Medical Supplies, Equipment, and Appliances. ()

a. For the initiation of home health services, excluding medical supplies, equipment, and appliances, the participant's physician must document that a face-to-face encounter that is related to the primary reason the patient requires home health services occurred with the participant no more than ninety (90) days before, or thirty (30) days after, the start of the home health services. Appropriate documentation must indicate the practitioner who conducted the encounter, and the date of the encounter as described in the CMS/Medicare DME coverage manual. ()

b. The face-to-face encounter may occur via telehealth, as defined in Title 54, Chapter 57, Idaho Code. ()

c. The face-to-face encounter may be performed by participant's physician, including an attending acute or post-acute physician, or one (1) of the following non-physician practitioners (NPP): ()

i. A nurse practitioner or clinical nurse specialist working in collaboration with the ordering physician; ()

ii. A nurse midwife; or ()

iii. A physician assistant under the supervision of the ordering physician. ()

d. If the face-to-face encounter is performed by an allowed NPP, the NPP must communicate the clinical findings of that face-to-face encounter to the ordering physician. ()

03. Face-to-Face Encounter for Home Health Medical Supplies, Equipment, and Appliances. ()

a. For the initiation of home health medical supplies, equipment, and appliances, the participant's physician, or a non-physician practitioner as authorized in Subsection 723.03 of this rule, must document that a face-

to-face encounter that is related to the primary reason the patient requires medical supplies, equipment, and appliances, occurred with the participant no more than six (6) months before the start of services. Appropriate documentation must indicate the practitioner who conducted the encounter, and the date of the encounter as described in the CMS/Medicare DME coverage manual. ()

b. The face-to-face encounter may occur via telehealth, as defined in Title 54, Chapter 57, Idaho Code. ()

c. The face-to-face encounter may be performed by participant's physician, including an attending acute or post-acute physician, or one of the following non-physician practitioners (NPP): ()

i. A nurse practitioner or clinical nurse specialist working in collaboration with the ordering physician; or ()

ii. A physician assistant under the supervision of the ordering physician. ()

d. If the face-to-face encounter is performed by an allowed NPP, the NPP must communicate the clinical findings of that face-to-face encounter to the ordering physician. ()

014. Home Health Plan of Care Review. ()

a. All home health services must be provided under a home health plan of care that is established prior to beginning treatment. The home health plan of care must be signed by the licensed, qualified professional who established the plan and must contain the information required under IDAPA 16.03.07, "Rules for Home Health Agencies." ()

b. All home health plans of care must be reviewed by the participant's physician as necessary, but at least every sixty (60) days; ~~and~~ for services, and at least annually for medical supplies, equipment, and appliances. (3-30-07)()

~~02. Review for Necessity. The need for medical supplies and equipment ordered by the participant's physician as required in the care of the participant and suitable for use in the home must be reviewed at least once every sixty (60) days.~~ (3-30-07)

(BREAK IN CONTINUITY OF SECTIONS)

732. THERAPY SERVICES: COVERAGE AND LIMITATIONS.

Therapy services are covered under these rules when delivered by a therapy professional and provided by one (1) of the following providers: outpatient hospitals, outpatient rehabilitation facilities, comprehensive outpatient rehabilitative facilities, nursing facilities, school-based services, Idaho Infant Toddler Program, independent practitioners, and home health agencies. Therapy services provided by a home health agency under a home health plan of care must meet the requirements found in Sections 730 through 739 of these rules, and the requirements found in Sections 720 through 729 of these rules. (7-1-16)()

01. Service Description: Occupational Therapy and Physical Therapy. Modalities, therapeutic procedures, tests, and measurements as described in the Physical Medicine and Rehabilitation Subsection and the Neurology and Neuromuscular Procedures Subsection of the Physician's Current Procedural Terminology (CPT Manual) are covered with the following limitations: (4-2-08)

a. Any evaluation or re-evaluation may only be performed by the therapist. Any changes in the participant's condition not consistent with planned progress or treatment goals necessitate a documented re-evaluation by the therapist before further treatment is carried out. (4-2-08)

b. Any CPT procedure code that falls under the heading of either, "Active Wound Care Management," or "Tests and Measurements," requires the therapist to have direct, one-to-one, patient contact. (4-2-08)

c. The therapist may be reimbursed for the technical component of muscle testing, joint range of motion, electromyography, or nerve velocity determinations as described in the CPT Manual when ordered by a physician, nurse practitioner, or physician assistant. (4-2-08)

d. Any assessment provided under the heading “Orthotic Management and Prosthetic Management” must be completed by the therapist. (4-2-08)

e. Any modality that is defined as “unlisted” in the CPT Manual requires prior authorization by the Department. In this case, the therapist and the physician, nurse practitioner, or physician assistant must provide information in writing to the Department that documents the medical necessity of the modality requested. (4-2-08)

f. The services of occupational or physical therapy assistants used when providing covered therapy benefits are included as part of the covered service. These services are billed by the supervising therapist. Therapy assistants may not provide evaluation services, make clinical judgments or decisions, or take responsibility for the service. The therapist has full responsibility for the service provided. Therapy assistants act at the direction and under the supervision of the treating therapist and in accordance with state licensure rules. (7-1-16)

02. Service Description: Speech-Language Pathology. Speech-language pathology services must be provided as defined in Section 730 of these rules. Services provided by speech-language pathology aides and assistants are considered unskilled services, and will be denied as not medically necessary if they are billed as speech-language pathology services. (7-1-16)

03. Non-Covered Services: Occupational Therapy, Physical Therapy, and Speech-Language Pathology. (4-2-08)

a. Continuing services for participants who do not exhibit the capability to achieve measurable improvement and who do not meet the criteria for a maintenance program. (7-1-16)

b. Services that address developmentally acceptable error patterns. (4-2-08)

c. Services that do not require the skills of a therapy professional. (7-1-16)

d. Massage, work hardening, and conditioning. (4-2-08)

e. Services that are not medically necessary, as defined in Section 011 of these rules. (4-2-08)

f. Duplicate services, as defined under Section 730 of these rules. (4-2-08)

g. Group therapy in settings other than school-based services and the Idaho Infant Toddler Program. (7-1-13)

h. Acupuncture (with or without electrical stimulation). (7-1-16)

i. Biofeedback, unless provided to treat urinary incontinence. (7-1-16)

j. Duplicate Services. (7-1-16)

k. Services that are considered to be experimental or investigational. (7-1-16)

l. Vocational Program. (7-1-16)

m. Vision Therapy. (7-1-16)

04. Service Limitations. (4-2-08)

a. Physical therapy (PT) and speech-language pathology (SLP) services are limited to a combined

annual dollar amount for all PT and SLP services. The Department will set the total amount based on the annual Medicare caps. The Department may authorize additional therapy services, when the services are determined to be medically necessary and supporting documentation is provided to the Department. (3-29-12)

b. Occupational therapy services are limited to an annual dollar amount set by the Department based on the annual Medicare caps. The Department may authorize additional therapy services, when the services are determined to be medically necessary and supporting documentation is provided to the Department. (3-29-12)

c. Exceptions to service limitations. (3-29-12)

i. Therapy provided by home health agencies is subject to the limitations on home health services contained in Section 722 of these rules. (3-29-12)

ii. Therapy provided through school-based services or the Idaho Infant Toddler Program is not included in the service limitations under Subsection 732.04 of this rule. (7-1-13)

iii. Therapy provided to EPSDT participants under the age of twenty-one (21) in accordance with the EPSDT requirements contained in Sections 881 through 883 of these rules, and in Section 1905(r) of the Social Security Act, will be authorized by the Department when additional therapy services are medically necessary. (3-29-12)

d. Feeding therapy services are covered for children with a diagnosed feeding disorder that results in a clinically significant deviation from normal childhood development. The provider of feeding therapy is an occupational therapist or speech therapist with training specific to feeding therapy. (7-1-16)

e. Maintenance therapy is covered when an individualized assessment of the participant's condition demonstrates that skilled care is required to carry out a safe and effective maintenance program. (7-1-16)

f. Telehealth modalities are covered to the extent they are allowed under the rules of the applicable board of licensing. The Department will define limitations on telehealth in the provider handbook to promote quality services and program integrity. (7-1-16)

733. THERAPY SERVICES: PROCEDURAL REQUIREMENTS.

The Department will pay for therapy services rendered by a therapy professional if such services are ordered by a physician, nurse practitioner, or physician assistant as part of a plan of care. (7-1-16)

01. Physician Orders. (4-2-08)

a. All therapy must be ordered by a physician, nurse practitioner, or physician assistant. Such orders must include at a minimum, the service to be provided, the frequency, and, where applicable, the expected duration of time for which the therapy will be needed. If the initial order is to evaluate and treat, but does not specify at least the type of service ordered and the frequency, then: (7-1-16)

i. The therapist may perform a therapy evaluation based on the initial physician order for the evaluation; and (7-1-16)

ii. The therapist must then develop a therapy plan of care based on that evaluation and send the plan to the ordering physician, nurse practitioner, or physician assistant and begin care; and (7-1-16)

iii. The physician, nurse practitioner, or physician assistant must either sign an order specifying the service to be provided, the frequency and the duration, or they must sign the therapy plan of care that includes that information within thirty (30) days for therapy to continue. No claims may be billed until the complete order or the plan of care is signed by the physician, nurse practitioner, or physician assistant. (7-1-16)

b. In the event that services are required for extended periods, these services must be reordered as necessary, but at least every ninety (90) days for all participants with the following exceptions: (5-8-09)

i. Therapy provided by home health agencies must be included in the home health plan of care and be reordered at least every sixty (60) days. (4-2-08)

ii. Therapy for individuals with long-term medical conditions, as documented by physician, nurse practitioner, or physician assistant, must be reordered at least every three hundred sixty-five (365) days. (7-1-16)

c. Therapy services provided under a home health plan of care must comply with the physician order requirements in Section 723 of these rules. ()

02. Level of Supervision. Supervision of physical therapist assistants and occupational therapist assistants by the physical therapist or occupational therapist must be done according to the rules of the applicable licensure board. (7-1-16)

03. Face-to-Face Encounter for Home Health Therapy Services. Therapy services provided under a home health plan of care must comply with the face-to-face encounter requirements in Section 723 of these rules. ()

034. Therapy Plan of Care. All therapy ~~is~~ services must be provided under a therapy plan of care that is established prior to beginning treatment. ()

a. The plan of care must be signed by the person who established the plan. ()

b. The plan of care must be consistent with the therapy evaluation and must contain, at a minimum: (7-1-16)()

a.i. Diagnoses; (7-1-16)

b.ii. Treatment goals that are measurable and pertain to the identified functional impairment(s); and (7-1-16)

c.iii. Type, frequency, and duration of therapy services. (7-1-16)

c. Therapy services provided under a home health plan of care must comply with the home health plan of care requirements in Section 723 of these rules. ()

(BREAK IN CONTINUITY OF SECTIONS)

751. DURABLE MEDICAL EQUIPMENT AND SUPPLIES: PARTICIPANT ELIGIBILITY RESPONSIBILITY.

The participant has a responsibility to reasonably protect and preserve equipment issued to him. Replacement of medical equipment or supplies that are lost, damaged or broken due to participant misuse or abuse are the responsibility of the participant. (3-30-07)()

752. DURABLE MEDICAL EQUIPMENT AND SUPPLIES: COVERAGE AND LIMITATIONS.

The Department will purchase or rent, when medically necessary, reasonable, and cost-effective, durable medical equipment (DME) and medical supplies ~~for participants residing in community settings including those provided by qualified home health providers under home health agency plans of care that meet the requirements found in Sections 720 through 724 of these rules~~ that are suitable for use in any setting in which normal life activities take place. Medical supplies, equipment, and appliances provided by a home health agency under a home health plan of care must meet the requirements found in Sections 750 through 779 of these rules and the requirements found in Sections 720 through 729 of these rules. (3-30-07)()

01. Medical Necessity Criteria -- Equipment and Supplies. Department standards for medical necessity are those national standards set by Centers for Medicare and Medicaid Services (CMS) in the ~~Medicare DME MAC Jurisdiction D Supplier Manual~~ CMS/Medicare DME coverage manual. Exceptions to Medicare

coverage are ~~contained in Section 752 of this chapter of rules. DME/medical supplies will be purchased or rented only if ordered in writing (signed and dated) by a physician as listed in the Medicare DME MAC Jurisdiction D Supplier Manual. Date of delivery is considered the date of service. The following information to support the medical necessity of the item(s) must be included in the physician's order and accompany all requests for prior authorization or be kept on file with the DME provider for items that do not require prior authorization: described in the Idaho Medicaid Provider Handbook available at: www.idmedicaid.com. Items for convenience, comfort, or cosmetic reasons are not covered.~~ (3-30-07)()

~~a. The participant's medical diagnosis including current information on the medical condition which requires the use of the supplies and/or medical equipment; and (3-30-07)~~

~~b. An estimate of the time period that the medical equipment or supply item will be necessary and frequency of use. As needed (PRN) orders must include the conditions for use and the expected frequency; and (3-30-07)~~

~~c. For medical equipment, a full description of the equipment needed. All modifications or attachments to basic equipment must be supported; and (3-30-07)~~

~~d. For medical supplies, the type and quantity of supplies necessary must be identified; and (3-30-07)~~

~~e. Documentation of the participant's medical necessity for the item, that meets coverage criteria in the CMS/Medicare DME coverage manual. (3-30-07)~~

~~f. Additional information may be requested by the Department for specific equipment and/or supplies such as, but not limited to, wheelchairs, apnea monitors, oximeters, hospital beds or equipment for which CMS/Medicare has established no coverage criteria. (3-30-07)~~

~~g. Items for convenience, comfort or cosmetic reasons are not covered. (3-30-07)~~

02. Prior Authorization -- Equipment and Supplies. ()

~~a. Unless otherwise specified by the Department in the provider handbook, durable medical equipment and medical supplies require prior authorization by the Department. ()~~

~~b. Each request for prior authorization must include all medical necessity documentation required under Section 753 of these rules. ()~~

~~c. The Medicaid fee schedule that identifies medical supplies, equipment, and appliances commonly ordered for Medicaid participants, is not a comprehensive list of all medical supplies, equipment, and appliances available to Medicaid participants. If a participant requires an item that is not listed on the fee schedule, a request may be submitted to the Department to assess items for coverage. This request must include justification of the medical necessity, amount of, and duration for the item or service. ()~~

023. Coverage Conditions -- Equipment. Medical equipment is subject to coverage limitations in the CMS/Medicare DME coverage manual. ~~Additional documentation requirements or coverage beyond those in the CMS/Medicare DME coverage manual include:~~ Exceptions to these coverage conditions and coverage conditions for medically necessary equipment not included in that manual are described in the Idaho Medicaid Provider Handbook available at: www.idmedicaid.com. Exceptions must be established using evidence-based or best clinical practice standards as determined by the Department. (3-30-07)()

~~a. Wheelchairs. The Department will provide the least costly wheelchair that is appropriate to meet the participant's medical needs. Wheelchair rental or purchase requires prior authorization by the Department. (3-30-07)~~

~~i. In addition to the physician's information, each request for purchase of a wheelchair must be accompanied by a written evaluation by a physical therapist or an occupational therapist. The evaluation must include documentation of the appropriateness and cost effectiveness of the specific wheelchair and all modifications~~

~~and/or attachments and its ability to meet the participant's long-term medical needs. For each request for a rental of a wheelchair, a physical therapist or an occupational therapist evaluation may be required on a case-by-case basis, to be determined by the Department; (3-30-07)~~

~~ii. Additional wheelchairs or seating systems may be considered within the five (5) year limitation with written documentation from the physician and a written evaluation from a physical therapist or an occupational therapist indicating the reason the current wheelchair no longer meets the participant's medical needs and cannot be modified to meet the participant's needs. All documentation required for a wheelchair or seating system purchase is required. (3-30-07)~~

~~b. Semi-electric hospital beds must be prior authorized by the Department and will be approved only when the physician documents that the participant meets the criteria set by the CMS/Medicare DME coverage manual and the participant lives in an independent living situation where there is no one available to provide assistance with a manual bed a major portion of the day. (3-30-07)~~

~~e. Communication devices will be considered for purchase by the Department under the following conditions: (3-30-07)~~

~~i. The need for the device must be based on a comprehensive history and physical. (3-30-07)~~

~~ii. The individual must lack the ability to communicate needs with the primary care physician or caregiver. (3-30-07)~~

~~iii. If the individual knows sign language or is capable of learning sign language a communication device would not be considered medically necessary. (3-30-07)~~

~~iv. The assessment and evaluation for the communication device must include comprehensive information as related to the individual's ability to communicate and review of the most cost effective devices to meet the individual's needs. Documentation must include: (3-30-07)~~

~~(1) Demographic and biographic summary; (3-30-07)~~

~~(2) Inventory of skills and sensory function; (3-30-07)~~

~~(3) Inventory of present and anticipated future communication needs; (3-30-07)~~

~~(4) Summary of device options; (3-30-07)~~

~~(5) Recommendation for device; and (3-30-07)~~

~~(6) Copy of individual treatment plan. (3-30-07)~~

~~v. Repairs to the device must be prior authorized and must not include modifications, technological improvements or upgrades. (3-30-07)~~

~~vi. Reimbursable supplies include rechargeable batteries, overlays, and symbols. (3-30-07)~~

~~vii. The use or provision of the system by any individual other than the participant for which the system was authorized is prohibited (3-30-07)~~

~~viii. Training and orientation in the use of the communication device may be billed as speech language pathology services by Medicaid providers of speech language pathology services. (4-2-08)~~

~~d. Maternity abdominal supports will be covered if the participant has: (3-30-07)~~

~~i. Vulvular varicosities; (3-30-07)~~

- ~~ii. Perineal edema; (3-30-07)~~
- ~~iii. Lymphedema; (3-30-07)~~
- ~~iv. External prolapse of the uterus or bladder; (3-30-07)~~
- ~~v. Hip separation; (3-30-07)~~
- ~~vi. Pubic symphysis separation; or (3-30-07)~~
- ~~vii. Severe abdominal or back strain. (3-30-07)~~
- ~~e. Apnea monitor when there is one (1) or more documented apneic episodes in the previous two (2) months. (4-2-08)~~

034. ~~Medical Supply Program Requirements~~ Coverage Conditions -- Supplies. ()

a. The Department will purchase no more than a one (1) month supply of necessary medical supplies per ~~calendar~~ month for the treatment or amelioration of a medical condition identified by the attending physician. Limitations for supplies follow the CMS/Medicare DME coverage manual. Supplies in excess of ~~those~~ the limitations in the CMS/Medicare DME coverage manual must be prior authorized by the Department. (3-30-07)()

b. Medical supplies are subject to the coverage limitations in the CMS/Medicare DME coverage manual. Exceptions to these coverage conditions and coverage conditions for medically necessary supplies not included in that manual are described in the Idaho Medicaid Provider Handbook available at: www.idmedicaid.com. Exceptions must be established using evidence-based or best clinical practice standards as determined by the Department. ()

~~a. Each request for prior authorization must include all information required in Subsection 752.01 of this rule. (3-30-07)~~

~~b. Supplies other than those listed below will require prior authorization: (3-30-07)~~

~~i. Catheter supplies including catheters, drainage tubes, collection bags, and other incidental supplies; (3-30-07)~~

~~ii. Cervical collars; (3-30-07)~~

~~iii. Colostomy and/or urostomy supplies; (3-30-07)~~

~~iv. Cotton tip applicators; (3-30-07)~~

~~v. Disposable supplies necessary to operate Department approved medical equipment such as suction catheters, syringes, saline solution, etc.; (3-30-07)~~

~~vi. Dressings and bandages to treat wounds, burns, or provide support to a body part; (3-30-07)~~

~~vii. Fluids for irrigation; (3-30-07)~~

~~viii. Incontinence supplies (See Subsection 752.04.b. of this rule for limitations); (3-30-07)~~

~~ix. Injectable supplies including normal saline and Heparin but excluding all other prescription drug items; (3-30-07)~~

~~x. Blood glucose or urine glucose checking/monitoring materials (tablets, tapes, strips, etc.), lancets; and (3-30-07)~~

- ~~xi. Therapeutic drug level home monitoring kits. (3-30-07)~~
- ~~xii. Oral, enteral, or parenteral nutritional products, see Subsection 752.04.a. of this rule additional documentation requirements. (3-30-07)~~

~~**04. Coverage Conditions – Supplies.** Medical supplies are covered when medical necessity criteria per the CMS/Medicare DME coverage manual or the following medical supply items are subject to the following limitations and additional documentation requirements: (3-30-07)~~

~~**a. Nutritional products.** Nutritional products will be purchased for participants who meet the CMS/Medicare DME coverage manual criteria, when the supplement is given by tube feeding or orally to meet caloric needs of the participant who cannot maintain growth, weight, and strength commensurate with his general condition from traditional foods alone. (3-30-07)~~

~~i. A nutritional plan must be developed and be on file with the provider and must include appropriate nutritional history, the participant's current height, weight, age and medical diagnosis. For participants under the age of twenty one (21), a growth chart including weight/height percentile must be included; (3-30-07)~~

~~ii. The plan must include goals for either weight maintenance and/or weight gain and must outline steps to be taken to decrease the participant's dependence on continuing use of nutritional supplements; (3-30-07)~~

~~iii. Documentation of evaluation and updating of the nutritional plan and assessment by a physician as needed but at least annually. (3-30-07)~~

~~**b. Incontinent supplies.** Incontinent supplies are covered for persons over four (4) years of age only and do not require prior authorization unless the participant needs supplies in excess of the following limitations: (3-30-07)~~

~~i. Diapers are restricted in number to two hundred forty (240) per month. If the physician documents that additional diapers are medically necessary, the Department may authorize additional amounts on an individual basis. (3-30-07)~~

~~ii. Disposable underpads are restricted to one hundred fifty (150) per month. (3-30-07)~~

~~iii. Pullups, for participants between the ages of four (4) and twenty one (21), are only allowed when the participant is participating in a formal toilet training program written by an Occupational Therapist, Qualified Intellectual Disabilities Professional (QIDP), or Developmental Specialist. Documentation for toilet training program must be updated on a yearly basis. (4-2-08)~~

753. DURABLE MEDICAL EQUIPMENT AND SUPPLIES: PROCEDURAL REQUIREMENTS.

~~**01. Medical Equipment Program Requirements Physician Orders.** All claims for durable medical equipment are subject to the following guidelines: (3-30-07)()~~

~~**a.** Unless specified by the Department, durable medical equipment requires prior authorization by the Department. All medical supplies, equipment, and appliances must be ordered by a physician. Such orders must meet the requirements described in the CMS/Medicare DME coverage manual. (3-30-07)()~~

~~**b.** Date of delivery is considered the date of service. ()~~

~~**c.** In the event that medical equipment and supplies are required for extended periods, these must be reordered as necessary, but at least annually, for all participants. ()~~

~~**d.** The following information to support the medical necessity of the item(s) must be included in the physician's order and accompany all requests for prior authorization, or be kept on file with the DME provider for items that do not require prior authorization: ()~~

i. The participant's medical diagnosis, including current information on the medical condition which requires the use of the supplies or medical equipment, or both; ()

ii. An estimate of the time period that the medical equipment or supply item will be necessary and frequency of use. As needed (PRN) orders must include the conditions for use and the expected frequency; ()

iii. For medical equipment, a full description of the equipment needed. All modifications or attachments to the basic equipment must be supported; ()

iv. For medical supplies, the type and quantity of supplies necessary must be identified; and ()

v. Documentation of the participant's medical necessity for the item, that meets coverage criteria in the CMS/Medicare DME coverage manual. ()

vi. Additional information may be requested by the Department for specific equipment or supplies, or both, including equipment for which CMS/Medicare has established no coverage criteria. ()

02. Face-to-Face Encounter for Home Health Medical Supplies, Equipment, and Appliances. Medical supplies, equipment, and appliances provided under a home health plan of care must comply with the face-to-face encounter requirements in Section 723 of these rules. ()

03. Plan of Care Requirements for Home Health Medical Supplies, Equipment, and Appliances. Medical supplies, equipment, and appliances provided under a home health plan of care must comply with the home health plan of care requirements in Section 723 of these rules. ()

04. Prior Authorizations. ()

a. Prior authorization means a written, faxed, or electronic approval from the Department that permits payment or coverage of a medical item or service that is covered only by such authorization. ()

i. Medicaid payment will be denied for the medical item or service or portions thereof which were provided prior to the submission of a valid prior authorization request. ()

ii. The provider may not bill the Medicaid participant for services not reimbursed by Medicaid solely because the authorization was not requested or obtained in a timely manner. An exception may be allowed on a case-by-case basis where, despite diligent efforts on the part of the provider to submit a request, or events beyond the provider's control prevented it. ()

b. An item or service will be deemed prior approved where the individual to whom the service was provided was not eligible for Medicaid at the time the service was provided, but was subsequently found eligible pursuant to IDAPA 16.03.05, "Rules Governing Eligibility for Aid to the Aged, Blind, and Disabled," and the medical item or service provided is approved by the Department by the same guidance that applies to other prior authorization requests. (3-30-07)()

c. A valid prior authorization request is a written, faxed, or electronic request from a provider of Medicaid for services that contains all information and documentation as required by these rules to justify the medical necessity, amount of and duration for the item or service. (3-30-07)

05. Notification of Changes to Prior Authorization Requirements. The Department will provide sixty (60) days notice of any substantive and significant changes to requirements for prior authorization in its provider handbook. The Department will provide a method to allow providers to provide input and comment on proposed changes. ()

06. Equipment Rental -- Purchase Procedures. Unless specified by the Department, all equipment must be rented except when it would be more cost effective to purchase it. Rentals are subject to the following guidelines: (3-30-07)()

~~ia.~~ Rental payments, including intermittent payments, are to be automatically applied to the purchase of the equipment. (3-30-07)

~~ib.~~ The Department may choose to continue to rent certain equipment without purchasing it. Such items include apnea monitors, ventilators, and other respiratory equipment. (3-30-07)

~~ic.~~ The total monthly rental cost of a DME item must not exceed one-tenth (1/10) of the total purchase price of the item. (3-30-07)

~~e.~~ *For codes that are manually priced, including miscellaneous codes, a copy of the manufacturer's suggested retail pricing (MSRP) or an invoice or quote from the manufacturer is required. Reimbursement will be seventy five percent (75%) of MSRP. If pricing documentation is the invoice, reimbursement will be at cost plus ten percent (10%), plus shipping (if that documentation is provided).* (3-30-07)

~~d.~~ *No reimbursement will be made for the cost of repairs (materials or labor) covered under the manufacturer's warranty. The date of purchase and the warranty period must be kept on file by the DME vendor. The following warranty periods are required to be provided on equipment purchased by the Department:* (3-30-07)

~~i.~~ *A power drive wheelchair must have a minimum one (1) year warranty period;* (3-30-07)

~~ii.~~ *An ultra light or high strength lightweight wheelchair must have a lifetime warranty period on the frame and crossbraces;* (3-30-07)

~~iii.~~ *All other wheelchairs must have a minimum one (1) year warranty period;* (3-30-07)

~~iv.~~ *All electrical components and new or replacement parts must have a minimum six (6) month warranty period;* (3-30-07)

~~v.~~ *All other DME not specified above must have a minimum one (1) year warranty period;* (3-30-07)

~~vi.~~ *If the manufacturer denies the warranty due to user misuse/abuse, that information must be forwarded to the Department at the time of the request for repair or replacement;* (3-30-07)

~~vii.~~ *The monthly rental payment must include a full service warranty. All routine maintenance, repairs, and replacement of rental equipment are the responsibility of the provider.* (3-30-07)

~~e.~~ *Covered equipment must meet the definition of durable medical equipment and be medically necessary as defined in Section 011 of these rules. All equipment must be prior authorized by the Department except for the following:* (3-30-07)

~~i.~~ *Bilirubin lights (require prior authorization after fourteen (14) days);* (3-30-07)

~~ii.~~ *Commode chairs and toilet seat extenders;* (3-30-07)

~~iii.~~ *Crutches and canes;* (3-30-07)

~~iv.~~ *Electric or hydraulic patient lift devices designed to transfer a person to and from bed to wheelchair or bathtub, but excluding lift chairs, devices attached to motor vehicles, and wall mounted chairs which lift persons up and down stairs;* (3-30-07)

~~v.~~ *Grab bars for the bathroom adjacent to the toilet and/or bathtub;* (3-30-07)

~~vi.~~ *Hand held showers;* (3-30-07)

~~vii.~~ *Head gear (protective);* (3-30-07)

~~viii.~~ *Hearing aids (see Section 742 of these rules for coverage and limitations);* (3-30-07)

- ~~ix. Home blood glucose monitoring equipment; (3-30-07)~~
- ~~x. Non-implantable intravenous infusion pumps, and/or NG/gastric tube feeding pumps, IV poles/stands, intrathecal administration kits; (3-30-07)~~
- ~~xi. Hand-held nebulizers and manual or electric percussor; (3-30-07)~~
- ~~xii. Medication organizers; (3-30-07)~~
- ~~xiii. Oxygen equipment; (3-30-07)~~
- ~~xiv. Compressors and breathing circuits, humidifiers used with IPPB or oxygen; (3-30-07)~~
- ~~xv. Sliding boards and bath benches/chairs; (3-30-07)~~
- ~~xvi. Suction pumps; (3-30-07)~~
- ~~xvii. Sheep skins, foam or gel pads or alternating pressure pad with pump for the prevention or treatment of decubitus ulcers; (3-30-07)~~
- ~~xviii. Traction equipment; and (3-30-07)~~
- ~~xix. Walkers. (3-30-07)~~

027. Notice of Decision. A Notice of Decision approving or denying a requested item will be issued to the participant by the Department. The participant has twenty-eight (28) days from the date of the denial to request an administrative fair hearing on the decision. Hearings will be conducted in accordance with IDAPA 16.05.03, "Rules Governing Contested Case Proceedings and Declaratory Rulings." ~~(3-30-07)~~()

754. (RESERVED)

755. DURABLE MEDICAL EQUIPMENT AND SUPPLIES: PROVIDER REIMBURSEMENT.

01. Items Included in Per Diem Excluded. No payment will be made for any participant's DME or medical supplies that are included in the per diem payment while such an individual is an inpatient in a hospital nursing facility or ICF/ID. (3-30-07)

02. Least Costly Limitation. When multiple features, models or brands of equipment or supplies are available, coverage will be limited to the least costly version that will reasonably and effectively meet the minimum requirements of the individual's medical needs. (3-30-07)

03. Billing Procedures. The Department will provide billing instructions to providers of DME/medical supplies. When prior authorization by the Department is required, the authorization number must be included on the claim form. (3-30-07)

04. Fees and Upper Limits. The Department will reimburse according to Section 230 of these rules. (3-30-07)

05. Date of Service. Unless specifically authorized by the Department the date of services for durable medical equipment and supplies is the date of delivery of the equipment and/or supply(s). The date of service cannot be prior to the vendor receiving all medical necessity documentation (3-30-07)

06. Manually Priced Codes. For codes that are manually priced, including miscellaneous codes, a copy of the manufacturer's suggested retail pricing (MSRP) or an invoice or quote from the manufacturer is required. Reimbursement will be seventy-five percent (75%) of MSRP. If the pricing documentation is the invoice, reimbursement will be at cost plus ten percent (10%), plus shipping, if that documentation is provided. ()

07. Warranties and Cost of Repairs. No reimbursement will be made for the cost of repairs (materials or labor, or both) covered under the manufacturer's warranty. The date of purchase and the warranty period must be kept on file by the DME vendor. The following warranty periods are required to be provided on equipment purchased by the Department: ()

a. A power drive wheelchair must have a minimum one (1) year warranty period; ()

b. An ultra-light or high-strength lightweight wheelchair must have a lifetime warranty period on the frame and crossbraces; ()

c. All other wheelchairs must have a minimum one (1) year warranty period; ()

d. All electrical components and new or replacement parts must have a minimum six (6) month warranty period; ()

e. All other DME not specified in Subsections 755.07.a. through 755.07.d. of this rule must have a minimum one (1) year warranty period; ()

f. If the manufacturer denies the warranty due to user misuse or abuse, or both, that information must be forwarded to the Department at the time of the request for repair or replacement; ()

g. The monthly rental payment must include a full service warranty. All routine maintenance, repairs, and replacement of rental equipment are the responsibility of the provider. ()

ELECTRONIC CODE OF FEDERAL REGULATIONS

e-CFR data is current as of May 13, 2016

Amendment

42 CFR--PART 440

View Printed Federal Register page 81 FR 5566 in PDF format.

Amendment(s) published February 2, 2016, in 81 FR 5566

EFFECTIVE DATES: July 1, 2016

2. Section 440.70 is amended by—

- a. Revising paragraph (b) introductory text.
- b. Revising paragraph (b)(3) introductory text.
- c. Redesignating paragraphs (b)(3)(i) and (ii) as paragraphs (b)(3)(iii) and (iv), respectively.
- d. Adding new paragraphs (b)(3)(i) and (ii) and paragraph (b)(3)(v).
- e. Adding paragraphs (c)(1) and (2).
- f. Adding paragraphs (f) and (g).

The revisions and additions read as follows:

§440.70 Home health services.

* * * * *

(b) Home health services include the following services and items. Paragraphs (b)(1), (2) and (3) of this section are required services and items that must be covered according to the home health coverage parameters. Services in paragraph (b)(4) of this section are optional. Coverage of home health services cannot be contingent upon the beneficiary needing nursing or therapy services.

* * * * *

(3) Medical supplies, equipment, and appliances suitable for use in any setting in which normal life activities take place, as defined at §440.70(c)(1).

(i) Supplies are health care related items that are consumable or disposable, or cannot withstand repeated use by more than one individual, that are required to address an individual medical disability, illness or injury.

(ii) Equipment and appliances are items that are primarily and customarily used to serve a medical purpose, generally are not useful to an individual in the absence of a disability, illness or injury, can withstand repeated use, and can be reusable or removable. State Medicaid coverage of equipment and appliances is not restricted to the items covered as durable medical equipment in the Medicare program.

* * * * *

(v) States can have a list of preapproved medical equipment supplies and appliances for administrative ease but States are prohibited from having absolute exclusions of coverage on medical equipment, supplies, or appliances. States must have processes and criteria for requesting medical equipment that is made available to individuals to request items not on the State's list. The procedure must use reasonable and specific criteria to assess items for coverage. When denying a request, a State must inform the beneficiary of the right to a fair hearing.

(c) * * *

(1) Nothing in this section should be read to prohibit a beneficiary from receiving home health services in any setting in which normal life activities take place, other than a hospital, nursing facility; intermediate care facility for individuals with intellectual disabilities; or any setting in which payment is or could be made under Medicaid for inpatient services that

include room and board. Home health services cannot be limited to services furnished to beneficiaries who are homebound.

(2) Additional services or service hours may, at the State's option, be authorized to account for medical needs that arise in the settings home health services are provided.

* * * * *

(f) No payment may be made for services referenced in paragraphs (b)(1) through (4) of this section, unless the physician referenced in paragraph (a)(2) of this section or for medical equipment, the allowed non-physician practitioner, as described in paragraph (f)(3)(ii) through (v), with the exception of certified nurse-midwives, as described in paragraph (f)(3)(iii) documents that there was a face-to-face encounter with the beneficiary that meets the following requirements:

(1) For the initiation of home health services, the face-to-face encounter must be related to the primary reason the beneficiary requires home health services and must occur within the 90 days before or within the 30 days after the start of the services.

(2) For the initiation of medical equipment, the face-to-face encounter must be related to the primary reason the beneficiary requires medical equipment and must occur no more than 6 months prior to the start of services.

(3) The face-to-face encounter may be conducted by one of the following practitioners:

(i) The physician referenced in paragraph (a)(2) of this section;

(ii) A nurse practitioner or clinical nurse specialist, as those terms are defined in section 1861(aa)(5) of the Act, working in collaboration with the physician referenced in paragraph (a) of this section, in accordance with State law;

(iii) A certified nurse midwife, as defined in section 1861(gg) of the Act, as authorized by State law;

(iv) A physician assistant, as defined in section 1861(aa)(5) of the Act, under the supervision of the physician referenced in paragraph (a) of this section; or

(v) For beneficiaries admitted to home health immediately after an acute or post-acute stay, the attending acute or post-acute physician.

(4) The allowed non-physician practitioner, as described in paragraph (f)(3)(ii) through (v) of this section, performing the face-to-face encounter must communicate the clinical findings of that face-to-face encounter to the ordering physician. Those clinical findings must be incorporated into a written or electronic document included in the beneficiary's medical record.

(5) To assure clinical correlation between the face-to-face encounter and the associated home health services, the physician responsible for ordering the services must:

(i) Document the face-to-face encounter which is related to the primary reason the patient requires home health services, occurred within the required timeframes prior to the start of home health services.

(ii) Must indicate the practitioner who conducted the encounter, and the date of the encounter.

(6) The face-to-face encounter may occur through telehealth, as implemented by the State.

(g)(1) No payment may be made for medical equipment, supplies, or appliances referenced in paragraph (b)(3) of this section to the extent that a face-to-face encounter requirement would apply as durable medical equipment (DME) under the Medicare program, unless the physician referenced in paragraph (a)(2) of this section or allowed non-physician practitioner, as described in paragraph (f)(3)(ii) through (v) of this section documents a face-to-face encounter with the beneficiary consistent with the requirements of paragraph (f) of this section except as indicated in paragraph (g)(2) of this section.

(2) The face-to-face encounter may be performed by any of the practitioners described in paragraph (f)(3) of this section, with the exception of certified nurse-midwives, as described in paragraph (f)(3)(iii) of this section.

Need assistance?

INCORPORATION BY REFERENCE SYNOPSIS

In compliance with Section 67-5223(4), Idaho Code, the following is a synopsis of the differences between the materials previously incorporated by reference in this rule that are currently in full force and effect and newly revised or amended versions of these same materials that are being proposed for incorporation by reference under this rulemaking.

The following agency of the State of Idaho has prepared this synopsis as part of the proposed rulemaking for the chapter cited here under the docket number specified:

**DEPARTMENT OF HEALTH AND WELFARE
IDAPA 16.03.09 -- MEDICAID BASIC PLAN BENEFITS
Proposed Rulemaking -- Docket No. 16-0309-1601**

(Include a brief description that explains the differences between the version of the materials or documents that are currently incorporated by reference and the materials or documents that are being proposed for adoption in this rulemaking.)

(You may use the following table or write a brief summary of the differences and attach to this document.)

Incorporated Document Version/URL	IDAPA Section Number	Current Version of Incorporated Document	Substantive Changes in New Incorporation by Reference Version
CMS/Medicare DME Coverage Manual, 2016	004.09 (004.04 in Proposed Rule)	Medicare Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) Jurisdiction D Supplier Manual 2007, as Amended.	Please see the attached summary of changes from Noridian, the publisher of the Supplier Manual.

Chapter Number	Chapter Name	Contents	Summary of Update
1	Introduction	What is Medicare	Updated deductible year and amount
1	Introduction	Noridian's Role as a DME MAC	Grammar correction
1	Introduction	Medicare Card	Formatting correction
2	Supplier Enrollment	National Provider Identifier	Formatting correction
2	Supplier Enrollment	Site Visit	Grammar correction
2	Supplier Enrollment	Participating/Non-Participation	Formatting correction
3	Documentation Requirements	Supplier Documentation	Grammar correction
3	Documentation Requirements	Orders	Changed wording of patient to beneficiary
3	Documentation Requirements	Dispensing Orders	Added link
3	Documentation Requirements	Detailed Written Orders	Adjusted wording to follow PIM
3	Documentation Requirements	Written Order Prior to Delivery	Adjusting wording to follow IOM
3	Documentation Requirements	Requirement of New Orders	Changed wording of patient to beneficiary
3	Documentation Requirements	Continued Use and Continued Medical Need	Grammar correction
3	Documentation Requirements	Documenting Repair Claims	Grammar correction and removed Q&A
3	Documentation Requirements	Refill Documentation	Formatting correction
3	Documentation Requirements	Beneficiary Authorization	Spelling correction

3	Documentation Requirements	Proof of Delivery	Changed wording of patient to beneficiary
3	Documentation Requirements	Proof of Delivery	Changed wording of patient to beneficiary
3	Documentation Requirements	ABN	Spelling and formatting correction
3	Documentation Requirements	Same/Similar Equipment and ABNs	Spelling correction
4	CMN & DIF	Evidence of Medical Necessity for oxygen CMN	Changed wording
4	CMN & DIF	CMN Common Scenarios	Spelling correction
8	EDI	Electronic Data Interchange/Common Electronic Data Interchange Contractor Overview	Spelling correction
9	DMEPOS Coverage, Benefit Categories, and Medical Policy	ADMC	Updated punctuation
9	DMEPOS Benefit Categories		Updated punctuation
13	Reopenings and Appeals	Reopenings	IOM update
15	Overpayment and Refunds	Immediate Recoupment Process/Immediate Offset Requests	Spelling correction
16	Coding	Modifiers	Add GX Modifier and description

IDAPA 16 - DEPARTMENT OF HEALTH AND WELFARE

16.03.09 - MEDICAID BASIC PLAN BENEFITS

DOCKET NO. 16-0309-1602

NOTICE OF RULEMAKING - PROPOSED RULE

AUTHORITY: In compliance with Section 67-5221(1), Idaho Code, notice is hereby given that this agency has initiated proposed rulemaking procedures. The action is authorized pursuant to Sections 56-202, 56-203, 56-250 through 56-257, and 56-260 through 56-266, Idaho Code; also 42 CFR 447, Sections 500 through 522.

PUBLIC HEARING SCHEDULE: The public hearings concerning this rulemaking will be held as follows:

Monday, October 17, 2016 2:30 pm (Local)	Tuesday, October 18, 2016 11:30 am (Local)	Wednesday, October 19, 2016 9:00 am (Local)
Medicaid Reg. VII Office 150 Shoup Avenue Large Conf. Rm., 2nd Floor Idaho Falls, ID	Medicaid Reg. I Office 1120 Ironwood Drive, Ste. 102 Coeur d'Alene, ID	Medicaid Central Office 3232 W. Elder Street Conf. Rm. D - West/East Boise, ID
TELECONFERENCE CALL-IN		

Toll Free: 1-877-820-7831 -- Participant Code: 701700

The hearing site will be accessible to persons with disabilities. Requests for accommodation must be made not later than five (5) days prior to the hearing, to the agency address below.

DESCRIPTIVE SUMMARY: The following is a nontechnical explanation of the substance and purpose of the proposed rulemaking:

Idaho is one of a few states that have already implemented the actual acquisition cost pricing methodology now required by Centers for Medicare and Medicaid Services (CMS) and has recognized significant savings as a result.

These rule changes clarify the Department's use of the appropriate pricing methodologies to provide reimbursement to pharmacies, reimbursement for physician-administered drugs, and reimbursement to 340B covered entities that already receive discounts from the drug manufacturers. These rule changes also align language and definitions with recent changes to federal regulations under 42 CFR 447.

FEE SUMMARY: The following is a specific description of the fee or charge imposed or increased: N/A

FISCAL IMPACT: The following is a specific description, if applicable, of any negative fiscal impact on the state general fund greater than ten thousand dollars (\$10,000) during the fiscal year as a result of this rulemaking:

This rulemaking has no fiscal impact to the state general fund or any other funds. This rulemaking is intended to be cost-neutral.

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220(2), Idaho Code, negotiated rulemaking was not conducted and was deemed not feasible as these changes bring the chapter into alignment with federal regulations.

INCORPORATION BY REFERENCE: No materials are being incorporated by reference in this rulemaking.

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Karen Westbrook at (208) 364-1960.

Anyone may submit written comments regarding this proposed rulemaking. All written comments must be

directed to the undersigned and must be delivered on or before October 26, 2016.

DATED this 30th day of August, 2016.

Tamara Prisock
DHW - Administrative Rules Unit
450 W. State Street - 10th Floor
P.O. Box 83720
Boise, ID 83720-0036
Phone: (208) 334-5500 / Fax: (208) 334-6558
E-mail: dhwrules@dhw.idaho.gov

THE FOLLOWING IS THE PROPOSED TEXT OF DOCKET NO. 16-0309-1602
(Only Those Sections With Amendments Are Shown.)

665. PRESCRIPTION DRUGS: PROVIDER REIMBURSEMENT.

All medications dispensed to Idaho Medicaid participants will be reimbursed based on actual acquisition costs. All medications administered to participants by physicians or other qualified and licensed providers must be reimbursed based on Medicare rates as directed in Section 56-265, Idaho Code, or if no Medicare rate is available, based on actual acquisition cost. Idaho Medicaid may require providers to supply documentation of their acquisition costs as described in the Medicaid Pharmacy Claims Submission Manual available at: https://idaho.fhsc.com/downloads/providers/IDRx_Pharmacy_Claims_Submission_Manual.pdf. Reimbursement is restricted to those drugs supplied from labelers that are participating in the CMS Medicaid Drug Rebate Program. ()

01. Pharmacy Reimbursement. Prescriptions not filled in accordance with the provisions of Subsection 664.02 of these rules will be subject to nonpayment or recoupment. The following protocol must be followed for proper reimbursement. (4-4-13)()

01a. Filing Claims. ~~Reimbursement is restricted to those drugs supplied from labelers that are participating in the CMS Medicaid Drug Rebate Program.~~ Pharmacists must file claims electronically with Department-approved software or by submitting the appropriate claim form to the fiscal contractor. Upon request, the contractor will provide pharmacies with a supply of claim forms. The form must include information described in the pharmacy guidelines issued by the Department. (4-4-13)()

02b. Claim Form Review. Each claim form may be subject to review by a contract claim examiner, a pharmaceutical consultant, or a medical consultant. (3-30-07)

03c. Billed Charges. A pharmacy's billed charges are not to exceed the usual and customary charges defined as the lowest charge by the provider to the general public for the same service including advertised specials. (3-30-07)

04d. Reimbursement. Reimbursement to pharmacies is limited to the lowest of the following: (3-30-07)

i. Federal Upper Limit (FUL), as established by the Centers for Medicare and Medicaid Services (CMS) of the U.S. Department of Health and Human Services, plus the dispensing fee assigned by the Department; (3-30-07)

ii. State Maximum Allowable Cost (SMAC), as established by the Department, plus the assigned dispensing fee; (3-30-07)

iii. Estimated Acquisition Cost (EAC), defined as the Average Actual Acquisition Cost (AAAC) based on results of the periodic state cost survey as defined in this rule, plus the assigned dispensing fee. In cases where no

AAAC is available, reimbursement will be the Wholesale Acquisition Cost (WAC). WAC will mean the price, paid by a wholesaler for the drugs purchased from the wholesaler's supplier, typically the manufacturer of the drug as published by a recognized compendia of drug pricing on the last day of the calendar quarter that corresponds to the calendar quarter; or (4-4-13)()

~~iv.~~ The pharmacy's billed charges as defined in Subsection 665.031 of this rule. (4-4-13)()

~~e.~~ Periodic State Cost Surveys. The Department will utilize periodic state cost surveys to obtain the most accurate pharmacy drug acquisition costs in establishing a pharmacy reimbursement fee schedule. Pharmacies participating in the Idaho Medicaid program are required to participate in these periodic state cost surveys by disclosing the costs of all drugs. A pharmacy that is non-responsive to the periodic state cost surveys can be disenrolled as a Medicaid provider by the Department. ()

~~05f.~~ **Dispensing Fee.** Only one (1) dispensing fee per month will be allowed for the dispensing of each maintenance drug to any participant as an outpatient or a resident in a care facility except: (4-4-13)

~~i.~~ Multiple dispensing of topical and injectable medication when dispensed in manufacturer's original package sizes, unless evidence exists, as determined by the Department, that the quantity dispensed does not relate to the prescriber's order; (3-30-07)

~~ii.~~ Multiple dispensing of oral liquid maintenance medication if a reasonable quantity, as determined by the Department, is dispensed at each filling; (3-30-07)

~~iii.~~ Multiple dispensing of tablets or capsules if the quantity needed for a thirty-four (34) day supply is excessively large or unduly expensive, in the judgment of the Department; or (3-30-07)

~~iv.~~ When the dose is being titrated for maximum therapeutic response with a minimum of adverse effects. (3-30-07)

~~06g.~~ **Claims Volume Survey for Tier-Based Dispensing Fees.** The Department will survey pharmacy providers to establish a dispensing fee for each provider. The dispensing fees will be paid based on the provider's total annual claims volume. The provider must return the claims volume survey to the Department no later than May 31st each year. Pharmacy providers who do not complete the annual claims volume survey will be assigned the lowest dispensing fee starting on July 1st until the next annual survey is completed. Based upon the annual claims volume of the enrolled pharmacy, the dispensing fee is provided online at: <http://healthandwelfare.idaho.gov/LinkClick.aspx?fileticket=iJDsiQavFLc%3d&tabid=119&mid=1111>. (4-4-13)

~~07h.~~ **Remittance Advice.** Claims are processed by computer, and payments are made directly to the pharmacy or its designated bank through electronic claims transfer. A remittance advice with detailed information of each claim transaction will accompany each payment made by the Department. (3-30-07)

02. 340B Covered Entity Reimbursement. ()

~~a.~~ Participation as a 340B Covered Entity. Medicaid will reimburse 340B covered entities as defined in Section 340B of the Public Health Service Act, codified under 42 U.S.C. 256b(a)(4), when the provider meets the following requirements: ()

~~i.~~ A 340B covered entity may receive reimbursement for drugs provided to Idaho Medicaid participants through the 340B drug pricing program if the 340B covered entity submits its unique 340B identification number issued by the Health Resources and Services Administration (HRSA) and a copy of its completed HRSA 340B registration to Idaho Medicaid. ()

~~ii.~~ A 340B covered entity that elects to provide drugs to Idaho Medicaid participants through the 340B drug pricing program must use 340B covered outpatient drugs for all dispensed or administered drugs, including those dispensed through the 340B covered entity's retail pharmacy or administered in an outpatient clinic. A 340B covered entity must ensure that a contract pharmacy does not dispense drugs, or receive Medicaid reimbursement for drugs, acquired by the 340B covered entity through the 340B drug pricing program. ()

iii. A 340B covered entity must provide Idaho Medicaid with thirty (30) days advance written notice of its intent to discontinue the provision of drugs acquired through the 340B drug pricing program to Idaho Medicaid participants. ()

b. Filing Claims. A 340B covered entity must file claims electronically with Department-approved software or by submitting the appropriate claim form to the fiscal contractor. The form must include information described in the pharmacy guidelines issued by the Department. ()

c. Claim Form Review. Each claim form may be subject to review by a contract claim examiner, a pharmaceutical consultant, or a medical consultant. ()

d. Billed Charges. A 340B covered entity's billed charges are not to exceed the entity's actual 340B drug acquisition cost. ()

e. Reimbursement. Reimbursement to 340B covered entities is limited to the actual 340B drug acquisition cost submitted (not to exceed the 340B ceiling price) plus the assigned dispensing fee. ()

f. Dispensing Fee. Only one (1) dispensing fee per month will be allowed for the dispensing of each maintenance drug to any participant as an outpatient or a resident in a care facility except: ()

i. Multiple dispensing of topical and injectable medication when dispensed in manufacturer's original package sizes, unless evidence exists, as determined by the Department, that the quantity dispensed does not relate to the prescriber's order; ()

ii. Multiple dispensing of oral liquid maintenance medication if a reasonable quantity, as determined by the Department, is dispensed at each filling; ()

iii. Multiple dispensing of tablets or capsules if the quantity needed for a thirty-four (34) day supply is excessively large or unduly expensive, in the judgment of the Department; or ()

iv. When the dose is being titrated for maximum therapeutic response with a minimum of adverse effects. ()

g. Claims Volume Survey for Tier-Based Dispensing Fees. A dispensing fee for each 340B covered entity will be established in accordance with this rule. ()

h. Remittance Advice. Claims are processed by computer, and payments are made directly to the 340B covered entity or its designated bank through electronic claims transfer. A remittance advice with detailed information of each claim transaction will accompany each payment made by the Department. ()

083. Return of Drugs. Drugs dispensed in unit dose packaging as defined by IDAPA 27.01.01, "Rules of the Idaho State Board of Pharmacy," ~~Subsection 156-05012~~, must be returned to the dispensing pharmacy when the participant no longer uses the medication as follows: (3-30-07)()

a. A pharmacy provider using unit dose packaging must comply with IDAPA 27.01.01, "Rules of the Idaho State Board of Pharmacy," ~~Subsection 1546-05~~. (3-30-07)()

b. The pharmacy provider that receives the returned drugs must credit the Department the amount billed for the cost of the drug less the dispensing fee. (3-30-07)

c. The pharmacy provider may receive a fee for acceptance of returned unused drugs. The value of the unused drug being returned must be cost effective as determined by the Department. (3-30-07)

~~**09. Periodic State Cost Surveys.** The Department will utilize periodic state cost surveys to obtain the most accurate pharmacy drug acquisition costs in establishing a pharmacy reimbursement fee schedule. Pharmacies participating in the Idaho Medicaid program are required to participate in these periodic state cost surveys by~~

~~disclosing the costs of all drugs net of any special discounts or allowances. A pharmacy that is non-responsive to the periodic state cost surveys can be disenrolled as a Medicaid provider by the Department. (4-4-13)~~

404. Cost Appeal Process. Cost appeals will be determined by the Department's process provided online at: <http://healthandwelfare.idaho.gov/LinkClick.aspx?fileticket=iJDsiQavFLc%3d&tabid=119&mid=1111>.
(4-4-13)



FEDERAL REGISTER

Vol. 81

Monday,

No. 20

February 1, 2016

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 447

Medicaid Program; Covered Outpatient Drugs; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS-2345-FC]

RIN 0938-AQ41

Medicaid Program; Covered Outpatient Drugs

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule implements provisions of the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively referred to as the Affordable Care Act) pertaining to Medicaid reimbursement for covered outpatient drugs (CODs). This final rule also revises other requirements related to CODs, including key aspects of their Medicaid coverage and payment and the Medicaid drug rebate program.

DATES: *Effective Date:* The final rule is effective on April 1, 2016.

Compliance Date: State Medicaid Agencies must comply with the requirements of § 447.512(b), § 447.518(a), and § 447.518(d) by submitting a State Plan Amendment (SPA) by June 30, 2017 to be effective no later than April 1, 2017.

Comment Date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on April 1, 2016. (See the **SUPPLEMENTARY INFORMATION** section of this final rule with comment period for a list of provisions open for comment.)

ADDRESSES: In commenting, please refer to file code CMS-2345-FC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to www.regulations.gov. Follow the instructions for "submitting a comment."

2. *By regular mail.* You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-2345-FC, P.O. Box 8013, Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-2345-FC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

FOR FURTHER INFORMATION CONTACT: Ruth Blatt, (410) 786-1767, for issues related to the definition of covered outpatient drug, including drug category, and rebates for line extensions.

Brian Du, (410) 786-6814, for issues related to the offset of rebates and collection of information.

Emeka Egwim (410-786-1092), for issues related to 340B and the Federal Upper Limits.

Lisa Ferrandi, (410) 786-5445, for issues related to 340B, rebates for drugs dispensed by Medicaid managed care organizations, requirements for states, the Collection of Information Requirements, and the Regulatory Impact Analysis.

Renee Hilliard, (410) 786-2991, for issues related to the definitions of states and United States.

Christine Hinds, (410) 786-4578, for issues related to authorized generics, nominal price, blood clotting factor, and exclusively pediatric drugs.

Gail Sexton, (410) 786-4583, for issues related to Federal upper limits and the definitions of actual acquisition cost and professional dispensing fee.

Terry Simananda, (410) 786-8144, or Wendy Tuttle, (410) 786-8690, for issues related to the determination of Average Manufacturer Price (AMP), identification of 5i drugs, the determination of Best Price, and manufacturer reporting requirements.

Andrea Wellington, (410) 786-3490 for issues related to the Regulatory Impact Analysis.

Wendy Tuttle, (410) 786-8690, for all other inquiries.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

Provisions open for comment: We will consider comments that are submitted as indicated above in the **DATES** and **ADDRESSES** sections on the following subject areas discussed in this final rule with comment period: The definition and identification of line extension drugs.

To assist readers in referencing sections contained in this document, we are providing the following Table of Contents.

Table of Contents

- I. Background
 - A. Introduction
 - B. Changes Made by the Affordable Care Act
 - C. Other Changes Concerning the Medicaid Drug Rebate Program

impact on small rural hospitals although they are required to place NDCs on all claims, including MCO claims, for physician administered drugs since states are required to bill manufacturers for rebates for these drugs. However, the impact on these entities would be minimal because there would be no other requirement except for providing NDC numbers for physician administered drugs. Therefore, the Secretary has determined that this final rule would not have a significant impact on the operations of a substantial number of small rural hospitals. At this time, we are unable to specifically estimate quantitative effects on small retail pharmacies, particularly those in low income areas where there are high concentrations of Medicaid beneficiaries.

VI. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule that includes a federal mandate that could result in expenditure in any 1 year by state, local or tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. In 2015, that threshold level is approximately \$144 million. This final rule imposes no mandate on drug manufacturers and other private entities. We believe the rule would not impose additional mandates on states and local governments. This final rule has tribal implications, and in accordance with E.O. 13175 and the HHS Tribal Consultation Policy (December 2010), CMS will consult with Tribal officials prior to the formal promulgation of this regulation.

VII. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. This final rule does not impose substantial direct requirement costs on state or local governments, preempts state law, or otherwise has federalism implications.

VIII. Congressional Review Act

This final regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been

transmitted to the Congress and the Comptroller General for review.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 447—PAYMENTS FOR SERVICES

■ 1. The authority citation for part 447 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

■ 2. Subpart I is revised to read as follows:

Subpart I—Payment for Drugs

Sec.

- 447.500 Basis and purpose.
- 447.502 Definitions.
- 447.504 Determination of average manufacturer price.
- 447.505 Determination of best price.
- 447.506 Authorized generic drugs.
- 447.507 Identification of inhalation, infusion, instilled, implanted, or injectable drugs (5i drugs).
- 447.508 Exclusion from best price of certain sales at a nominal price.
- 447.509 Medicaid drug rebates (MDR).
- 447.510 Requirements for manufacturers.
- 447.511 Requirements for States.
- 447.512 Drugs: Aggregate upper limits of payment.
- 447.514 Upper limits for multiple source drugs.
- 447.516 Upper limits for drugs furnished as part of services.
- 447.518 State plan requirements, findings, and assurances.
- 447.520 Federal Financial Participation (FFP): Conditions relating to physician-administered drugs.
- 447.522 Optional coverage of investigational drugs and other drugs not subject to rebate.

§ 447.500 Basis and purpose.

(a) *Basis.* This subpart:

(1) Interprets those provisions of section 1927 of the Act that set forth requirements for drug manufacturers' calculating and reporting average manufacturer prices (AMPs) and best prices and that set upper payment limits for covered outpatient drugs.

(2) Implements section 1903(i)(10) of the Act with regard to the denial of Federal financial participation (FFP) in

expenditures for certain physician-administered drugs.

(3) Implements section 1902(a)(54) of the Act with regard to a State plan that provides covered outpatient drugs.

(4) Implements section 1903(m)(2)(A)(xiii) of the Act, in part, and section 1927(b) of the Act with regard to rebates for covered outpatient drugs dispensed to individuals eligible for medical assistance who are enrolled in Medicaid managed care organizations (MCOs).

(5) Implements section 1902(a)(30)(A) of the Act with regard to the efficiency, economy, and quality of care in the context of payments for covered outpatient drugs.

(b) *Purpose.* This subpart specifies certain requirements in the Social Security Act, including changes from the Affordable Care Act and other requirements pertaining to Medicaid payment for drugs.

§ 447.502 Definitions.

For the purpose of this subpart, the following definitions apply:

Actual acquisition cost (AAC) means the agency's determination of the pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific manufacturers.

Authorized generic drug means any drug sold, licensed, or marketed under a new drug application (NDA) approved by the Food and Drug Administration (FDA) under section 505(c) of the Federal Food, Drug and Cosmetic Act (FFDCA) that is marketed, sold or distributed under a different labeler code, product code, trade name, trademark, or packaging (other than repackaging the listed drug for use in institutions) than the brand name drug.

Bona fide service fee means a fee paid by a manufacturer to an entity that represents fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that is not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug. The fee includes, but is not limited to, distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative service agreements and patient care programs (such as medication compliance programs and patient education programs).

Brand name drug means a single source or innovator multiple source drug.

Bundled sale means any arrangement regardless of physical packaging under

which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit national drug code (NDC) level) or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement.

(1) The discounts in a bundled sale, including those discounts resulting from a contingent arrangement, are allocated proportionally to the total dollar value of the units of all drugs or products sold under the bundled arrangement.

(2) For bundled sales where multiple drugs are discounted, the aggregate value of all the discounts in the bundled arrangement must be proportionally allocated across all the drugs or products in the bundle.

Clotting factor means a hemophilia clotting factor for which a separate furnishing payment is made under section 1842(o)(5) of the Act and which is included on a list of such factors specified and updated regularly by CMS and posted on the CMS Web site.

Consumer Price Index—Urban (CPI-U) means the index of consumer prices developed and updated by the U.S. Department of Labor. It is the CPI for all urban consumers (U.S. average) for the month before the beginning of the calendar quarter for which the rebate is paid.

Covered outpatient drug means, of those drugs which are treated as a prescribed drug for the purposes of section 1905(a)(12) of the Act, a drug which may be dispensed only upon a prescription (except as provided in paragraphs (2) and (3) of this definition).

(1) A drug can only be considered a covered outpatient drug if it:

(i) Is approved for safety and effectiveness as a prescription drug by the FDA under section 505 or 507 of the FFDCA or under section 505(j) of the FFDCA;

(ii) Was commercially used or sold in the United States before the enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the meaning described in FDA regulations at 21 CFR 310.6(b)(1)) to such a drug, and which has not been the subject of a final determination by the Secretary that it is a “new drug” (within the meaning of section 201(p) of the FFDCA) or an action brought by the Secretary under sections 301, 302(a), or

304(a) of FFDCA to enforce section 502(f) or 505(a) of the FFDCA;

(iii) Is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need or is identical, similar, or related (within the meaning described in FDA regulations at 21 CFR 310.6(b)(1)) to such a drug or for which the Secretary has not issued a notice for an opportunity for a hearing under section 505(e) of the FFDCA on a proposed order of the Secretary to withdraw approval of an application for such drug under section 505(e) of the FFDCA because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling;

(iv) Is a biological product other than a vaccine that may only be dispensed upon a prescription and is licensed under section 351 of the Public Health Service Act (PHSA) and is produced at an establishment licensed under section 351 of the PHSA to produce such product; or

(v) Is insulin certified under section 506 of the FFDCA.

(2) A covered outpatient drug does not include any drug, biological product, or insulin provided as part of or incident to and in the same setting as any of the following services (and for which payment may be made as part of that service instead of as a direct reimbursement for the drug):

- (i) Inpatient Services;
- (ii) Hospice Services;
- (iii) Dental Services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs;
- (iv) Physician services;
- (v) Outpatient hospital services;
- (vi) Nursing facility and services provided by an intermediate care facility for individuals with intellectual disabilities;
- (vii) Other laboratory and x-ray services; or
- (viii) Renal dialysis.

(3) A covered outpatient drug does not include:

- (i) Any drug product, prescription or over-the-counter (OTC), for which an NDC number is not required by the FDA;
- (ii) Any drug product for which a manufacturer has not submitted to CMS evidence to demonstrate that the drug product satisfies the criteria in paragraph (1) of this definition;
- (iii) Any drug product or biological used for a medical indication which is not a medically accepted indication; or
- (iv) Over-the-counter products that are not drugs.

Customary prompt pay discount means any discount off of the purchase price of a drug routinely offered by the manufacturer to a wholesaler for prompt payment of purchased drugs within a specified timeframe and consistent with customary business practices for payment.

Innovator multiple source drug means a multiple source drug that was originally marketed under an original new drug application (NDA) approved by FDA, including an authorized generic drug. It also includes a drug product marketed by any cross-licensed producers, labelers, or distributors operating under the NDA and a covered outpatient drug approved under a biologics license application (BLA), product license application (PLA), establishment license application (ELA) or antibiotic drug application (ADA). For purposes of this definition and the Medicaid drug rebates (MDR) program, an original NDA means an NDA, other than an Abbreviated New Drug Application (ANDA), approved by the FDA for marketing, unless CMS determines that a narrow exception applies.

Lagged price concession means any discount or rebate that is realized after the sale of the drug, but does not include customary prompt pay discounts.

Manufacturer means any entity that holds the NDC for a covered outpatient drug or biological product and meets the following criteria:

(1) Is engaged in the production, preparation, propagation, compounding, conversion, or processing of covered outpatient drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis; or

(2) Is engaged in the packaging, repackaging, labeling, relabeling, or distribution of covered outpatient drug products and is not a wholesale distributor of drugs or a retail pharmacy licensed under State law.

(3) For authorized generic products, the term “manufacturer” will also include the original holder of the NDA.

(4) For drugs subject to private labeling arrangements, the term “manufacturer” will also include the entity under whose own label or trade name the product will be distributed.

Multiple source drug means, for a rebate period, a covered outpatient drug for which there is at least one other drug product which meets the following criteria:

(1) Is rated as therapeutically equivalent as reported in the FDA’s

“Approved Drug Products with Therapeutic Equivalence Evaluations” which is available at <http://www.accessdata.fda.gov/scripts/cder/ob/>.

(2) Is pharmaceutically equivalent and bioequivalent, as determined by the FDA.

(3) Is sold or marketed in the United States during the rebate period.

National drug code (NDC) means the numerical code maintained by the FDA that includes the labeler code, product code, and package code. For purposes of this subpart, the NDC is considered to be an 11-digit code, unless otherwise specified in this subpart as being without regard to package size (that is, the 9-digit numerical code).

National rebate agreement means the rebate agreement developed by CMS and entered into by CMS on behalf of the Secretary or his or her designee and a manufacturer to implement section 1927 of the Act.

Nominal price means a price that is less than 10 percent of the average manufacturer price (AMP) in the same quarter for which the AMP is computed.

Noninnovator multiple source drug means:

(1) A multiple source drug that is not an innovator multiple source drug or a single source drug;

(2) A multiple source drug that is marketed under an ANDA or an abbreviated antibiotic drug application;

(3) A covered outpatient drug that entered the market before 1962 that was not originally marketed under an NDA;

(4) Any drug that has not gone through an FDA approval process, but otherwise meets the definition of covered outpatient drug; or

(5) If any of the drug products listed in this definition of a noninnovator multiple source drug subsequently receives an NDA or ANDA approval from FDA, the product's drug category changes to correlate with the new product application type.

Oral solid dosage form means capsules, tablets, or similar drugs products intended for oral use as defined in accordance with FDA regulation at 21 CFR 206.3 that defines solid oral dosage form.

Over-the-counter (OTC) drug means a drug that is appropriate for use without the supervision of a health care professional such as a physician, and which can be purchased by a consumer without a prescription.

Pediatric indication means a specifically stated indication for use by the pediatric age group meaning from birth through 16 years of age, or a subset of this group as specified in the “Indication and Usage” section of the

FDA approved labeling, or in an explanation elsewhere in the labeling that makes it clear that the drug is for use only in a pediatric age group, or a subset of this group.

Professional dispensing fee means the professional fee which:

(1) Is incurred at the point of sale or service and pays for costs in excess of the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed;

(2) Includes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary. Pharmacy costs include, but are not limited to, reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling, physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy; and

(3) Does not include administrative costs incurred by the State in the operation of the covered outpatient drug benefit including systems costs for interfacing with pharmacies.

Rebate period means a calendar quarter.

Single source drug means a covered outpatient drug that is produced or distributed under an original NDA approved by FDA and has an approved NDA number issued by FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the NDA. It also includes a covered outpatient drug approved under a biologics license application (BLA), product license application (PLA), establishment license application (ELA), or antibiotic drug application (ADA). For purposes of this definition and the MDR program, an original NDA means an NDA, other than an ANDA, approved by the FDA for marketing, unless CMS determines that a narrow exception applies.

States means the 50 States and the District of Columbia and beginning April 1, 2017, also includes the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa.

United States means the 50 States and the District of Columbia and beginning April 1, 2017 also includes the Commonwealth of Puerto Rico, the

Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa.

Wholesaler means a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies, including but not limited to manufacturers, repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including manufacturer's and distributor's warehouses, chain drug warehouses, and wholesale drug warehouses), independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions.

§ 447.504 Determination of average manufacturer price.

(a) *Definitions.* For the purpose of this section, the following definitions apply:

Average manufacturer price (AMP) means, for a covered outpatient drug of a manufacturer (including those sold under an NDA approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act), the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer.

Average unit price means a manufacturer's sales included in AMP less all required adjustments divided by the total units sold and included in AMP by the manufacturer in a quarter.

Charitable and not-for profit pharmacies means organizations exempt from taxation as defined by section 501(c)(3) of the Internal Revenue Code of 1986.

Insurers means entities that are responsible for payment to pharmacies for drugs dispensed to their members, and do not take actual possession of these drugs or pass on manufacturer discounts or rebates to pharmacies.

Net sales means quarterly gross sales revenue less cash discounts allowed, except customary prompt pay discounts extended to wholesalers, and all other price reductions (other than rebates under section 1927 of the Act or price reductions specifically excluded by statute or regulation) which reduce the amount received by the manufacturer.

Retail community pharmacy means an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices. Such term does not include a pharmacy that dispenses prescription medications to patients primarily through the mail, nursing home pharmacies, long-term

care facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies, or pharmacy benefit managers.

(b) *Sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions included in AMP.* Except for those sales, nominal price sales, and associated discounts, rebates, payments or other financial transactions identified in paragraph (c) of this section, AMP for covered outpatient drugs includes the following sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions:

(1) Sales to wholesalers for drugs distributed to retail community pharmacies.

(2) Sales to other manufacturers who act as wholesalers for drugs distributed to retail community pharmacies.

(3) Sales to retail community pharmacies (including those sales, nominal price sales, and associated discounts, rebates (other than rebates under section 1927 of the Act or as specified in regulations), payments, or other financial transactions that are received by, paid by, or passed through to retail community pharmacies).

(c) *Sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions excluded from AMP.* AMP excludes the following sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions:

(1) Any prices on or after October 1, 1992, to the Indian Health Service (IHS), the Department of Veterans Affairs (DVA), a State home receiving funds under 38 U.S.C. 1741, the Department of Defense (DoD), the Public Health Service (PHS), or a covered entity described in section 1927(a)(5)(B) of the Act (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA).

(2) Any prices charged under the Federal Supply Schedule (FSS) of the General Services Administration (GSA).

(3) Any depot prices (including TRICARE) and single award contract prices, as defined by the Secretary, of any agency of the Federal government.

(4) Sales outside the United States.

(5) Sales to hospitals.

(6) Sales to health maintenance organizations (HMOs) (including managed care organizations (MCOs)), including HMO or MCO operated pharmacies.

(7) Sales to long-term care providers, including nursing facility pharmacies, nursing home pharmacies, long-term care facilities, contract pharmacies for the nursing facility where these sales

can be identified with adequate documentation, and other entities where the drugs are dispensed through a nursing facility pharmacy, such as assisted living facilities.

(8) Sales to mail order pharmacies.

(9) Sales to clinics and outpatient facilities (for example, surgical centers, ambulatory care centers, dialysis centers, and mental health centers).

(10) Sales to government pharmacies (for example, a Federal, State, county, or municipal-owned pharmacy).

(11) Sales to charitable pharmacies.

(12) Sales to not-for-profit pharmacies.

(13) Sales, associated rebates, discounts, or other price concessions paid directly to insurers.

(14) Bona fide service fees, as defined in § 447.502, paid by manufacturers to wholesalers or retail community pharmacies.

(15) Customary prompt pay discounts extended to wholesalers.

(16) Reimbursement by the manufacturer for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction, but only to the extent that such payment covers only those costs.

(17) Associated discounts, rebates, or other price concessions provided under the Medicare Coverage Gap Discount Program under section 1860D-14A of the Act.

(18) Payments received from and rebates and discounts provided to pharmacy benefit manufacturers (PBMs).

(19) Rebates under the national rebate agreement or a CMS-authorized State supplemental rebate agreement paid to State Medicaid Agencies under section 1927 of the Act.

(20) Sales to hospices (inpatient and outpatient).

(21) Sales to prisons.

(22) Sales to physicians.

(23) Direct sales to patients.

(24) Free goods, not contingent upon any purchase requirement.

(25) Manufacturer coupons to a consumer redeemed by the manufacturer, agent, pharmacy or another entity acting on behalf of the manufacturer, but only to the extent that the full value of the coupon is passed on to the consumer and the pharmacy, agent, or other AMP-eligible entity does not receive any price concession.

(26) Manufacturer-sponsored programs that provide free goods, including but not limited to vouchers

and patient assistance programs, but only to the extent that: The voucher or benefit of such a program is not contingent on any other purchase requirement; the full value of the voucher or benefit of such a program is passed on to the consumer; and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(27) Manufacturer-sponsored drug discount card programs, but only to the extent that the full value of the discount is passed on to the consumer and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(28) Manufacturer-sponsored patient refund/rebate programs, to the extent that the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent, or other AMP eligible entity does not receive any price concessions.

(29) Manufacturer copayment assistance programs, to the extent that the program benefits are provided entirely to the patient and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(30) Any rebates, discounts, or price concessions provided to a designated State Pharmacy Assistance Program (SPAP).

(d) *Sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions included in AMP for 5i drugs that are not generally dispensed through retail community pharmacies.* Except for those sales, nominal price sales, and associated discounts, rebates, payments, and other financial transactions identified in paragraph (e) of this section, AMP for inhalation, infusion, instilled, implanted, or injectable drugs (5i) covered outpatient drugs identified in accordance with § 447.507 shall include sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions to all entities specified in paragraph (b) of this section, as well as the following sales, nominal price sales, and associated discounts, rebates, payments, or other financial transactions:

(1) Sales to physicians.

(2) Sales to pharmacy benefit managers.

(3) Sales to health maintenance organizations (HMOs), including managed care organizations (MCOs).

(4) Sales to insurers (except for rebates under section 1927 of the Act and this subpart).

(5) Sales to hospitals.

(6) Sales to clinics and outpatient facilities (for example, surgical centers,

ambulatory care centers, dialysis centers, mental health centers).

(7) Sales to mail order pharmacies.

(8) Sales to long-term care providers, including nursing facility pharmacies, nursing home pharmacies, long-term care facilities, contract pharmacies for the nursing facility where these sales can be identified with adequate documentation, and other entities where the drugs are dispensed through a nursing facility pharmacy, such as assisted living facilities.

(9) Sales to hospices (inpatient and outpatient).

(10) Sales to manufacturers, or any other entity that does not conduct business as a wholesaler or retail community pharmacy.

(e) *Sales, nominal price sales, and associated discounts, rebates, payments, or other transactions excluded from AMP for 5i drugs that are not generally dispensed through retail community pharmacies.* AMP for 5i covered outpatient drugs identified in accordance with § 447.507 excludes the following sales, nominal price sales, and associated discounts, rebates, or other financial transactions:

(1) Any prices on or after October 1, 1992, to the Indian Health Service (IHS), the Department of Veterans Affairs (DVA), a State home receiving funds under 38 U.S.C. 1741, the Department of Defense (DoD), the Public Health Service (PHS), or a covered entity described in section 1927(a)(5)(B) of the Act (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA).

(2) Any prices charged under the Federal Supply Schedule (FSS) of the General Services Administration (GSA).

(3) Any depot prices (including TRICARE) and single award contract prices, as defined by the Secretary, of any agency of the Federal government.

(4) Sales outside the United States.

(5) Bona fide service fees as defined in § 447.502 paid by manufacturers to wholesalers or retail community pharmacies.

(6) Customary prompt pay discounts extended to wholesalers.

(7) Reimbursement by the manufacturer for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction, but only to the extent that such payment covers only these costs.

(8) Any prices charged which are negotiated by a prescription drug plan under Part D of title XVIII, by any MA-

PD plan under Part C of such title for covered Part D drugs, or by a Qualified Retiree Prescription Drug Plan (as defined in section 1860D-22(a)(2) of the Act) for such drugs on behalf of individuals entitled to benefits under Part A or enrolled under Part B of Medicare, or any discounts provided by manufacturers under the Medicare coverage gap discount program under section 1860D-14A of the Act.

(9) Rebates under the national rebate agreement or a CMS-authorized State supplemental rebate agreement paid to State Medicaid Agencies under section 1927 of the Act.

(10) Any rebates, discounts, or price concessions provided to a designated State Pharmacy Assistance Program (SPAP).

(11) Sales to patients.

(12) Free goods, not contingent upon any purchase requirement.

(13) Manufacturer coupons to a consumer redeemed by the manufacturer, agent, pharmacy or another entity acting on behalf of the manufacturer, but only to the extent that the full value of the coupon is passed on to the consumer and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(14) Manufacturer-sponsored programs that provide free goods, including, but not limited to vouchers and patient assistance programs, but only to the extent that the voucher or benefit of such a program is not contingent on any other purchase requirement; the full value of the voucher or benefit of such a program is passed on to the consumer; and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(15) Manufacturer-sponsored drug discount card programs, but only to the extent that the full value of the discount is passed on to the consumer and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(16) Manufacturer-sponsored patient refund/rebate programs, to the extent that the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent, or other AMP eligible entity does not receive any price concessions.

(17) Manufacturer copayment assistance programs, to the extent that the program benefits are provided entirely to the patient and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(18) Sales to government pharmacies (for example, a Federal, State, county, or municipal-owned pharmacy).

(19) Sales to charitable pharmacies.

(20) Sales to not-for-profit pharmacies.

(f) *Further clarification of AMP calculation.* (1) AMP includes cash discounts except customary prompt pay discounts extended to wholesalers, free goods that are contingent on any purchase requirement, volume discounts, chargebacks that can be identified with adequate documentation, incentives, administrative fees, service fees, distribution fees (other than bona fide service fees), and any other rebates, discounts or other financial transactions, other than rebates under section 1927 of the Act, which reduce the price received by the manufacturer for drugs distributed to retail community pharmacies.

(2) Quarterly AMP is calculated as a weighted average of monthly AMPs in that quarter.

(3) The manufacturer must adjust the AMP for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices actually realized, to the extent that such cumulative discounts, rebates, or other arrangements are not excluded from the determination of AMP by statute or regulation.

§ 447.505 Determination of best price.

(a) *Definitions.* For the purpose of this section, the following definitions apply:

Best price means, for a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for an authorized generic drug), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the United States in any pricing structure (including capitated payments), in the same quarter for which the AMP is computed.

Provider means a hospital, HMO, including an MCO, or entity that treats or provides coverage or services to individuals for illnesses or injuries or provides services or items in the provision of health care.

(b) *Prices included in best price.* Except for those prices identified in paragraph (c) of this section, best price for covered outpatient drugs includes all prices, including applicable discounts, rebates, or other transactions that adjust prices either directly or indirectly to the best price-eligible entities listed in paragraph (a) of this section.

(c) *Prices excluded from best price.* Best price excludes the following:

(1) Any prices on or after October 1, 1992, charged to the IHS, the DVA, a State home receiving funds under 38 U.S.C. 1741, the DoD, or the PHS.

(2) Any prices charged to a covered entity described in section 1927(a)(5)(B) of the Act (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the PHSA).

(3) Any prices charged under the FSS of the GSA.

(4) Any prices, rebates, or discounts provided to a designated State Pharmacy Assistance Program (SPAP).

(5) Any depot prices (including TRICARE) and single award contract prices, as defined by the Secretary, of any agency of the Federal government.

(6) Any prices charged which are negotiated by a prescription drug plan under Part D of title XVIII, by any MA-PD plan under Part C of such title for covered Part D drugs, or by a Qualified Retiree Prescription Drug Plan (as defined in section 1860D-22(a)(2) of the Act) for such drugs on behalf of individuals entitled to benefits under Part A or enrolled under Part B of Medicare, or any discounts provided by manufacturers under the Medicare coverage gap discount program under section 1860D-14A of the Act.

(7) Rebates under the national rebate agreement or a CMS-authorized supplemental rebate agreement paid to State Medicaid Agencies under section 1927 of the Act.

(8) Manufacturer-sponsored drug discount card programs, but only to the extent that the full value of the discount is passed on to the consumer and the pharmacy, agent, or other entity does not receive any price concession.

(9) Manufacturer coupons to a consumer redeemed by a consumer, agent, pharmacy, or another entity acting on behalf of the manufacturer; but only to the extent that the full value of the coupon is passed on to the consumer, and the pharmacy, agent, or other entity does not receive any price concession.

(10) Manufacturer copayment assistance programs, to the extent that the program benefits are provided entirely to the patient and the pharmacy, agent, or other entity does not receive any price concession.

(11) Manufacturer-sponsored patient refund or rebate programs, to the extent that the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent, or other entity does not receive any price concession.

(12) Manufacturer-sponsored programs that provide free goods, including but not limited to vouchers and patient assistance programs, but

only to the extent that the voucher or benefit of such a program is not contingent on any other purchase requirement; the full value of the voucher or benefit of such a program is passed on to the consumer; and the pharmacy, agent, or other entity does not receive any price concession.

(13) Free goods, not contingent upon any purchase requirement.

(14) Reimbursement by the manufacturer for recalled, damaged, expired, or otherwise unsalable returned goods, including, but not limited to, reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction but only to the extent that such payment covers only these costs.

(15) Nominal prices to certain entities as set forth in § 447.508.

(16) Bona fide service fees as defined in § 447.502.

(17) PBM rebates, discounts, or other financial transactions except their mail order pharmacy's purchases or where such rebates, discounts, or other financial transactions are designed to adjust prices at the retail or provider level.

(18) Sales outside the United States.

(19) Direct sales to patients.

(d) *Further clarification of best price.*

(1) Best price is net of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, customary prompt pay discounts, chargebacks, incentives, promotional fees, administrative fees, service fees (except bona fide service fees), distribution fees, and any other discounts or price reductions and rebates, other than rebates under section 1927 of the Act, which reduce the price available from the manufacturer.

(2) Best price must be determined on a unit basis without regard to package size, special packaging, labeling, or identifiers on the dosage form or product or package.

(3) The manufacturer must adjust the best price for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices available from the manufacturer.

§ 447.506 Authorized generic drugs.

(a) *Definitions.* For the purpose of this section, the following definitions apply:

Primary manufacturer means a manufacturer that holds the NDA of the authorized generic drug.

Secondary manufacturer of an authorized generic drug means a manufacturer that is authorized by the primary manufacturer to sell the drug but does not hold the NDA.

(b) *Inclusion of authorized generic drugs in AMP by a primary manufacturer.* The primary manufacturer must include in its calculation of AMP its sales of authorized generic drugs that have been sold or licensed to a secondary manufacturer, acting as a wholesaler for drugs distributed to retail community pharmacies, or when the primary manufacturer holding the NDA sells directly to a wholesaler.

(c) *Inclusion of authorized generic drugs in best price by a primary manufacturer.* A primary manufacturer holding the NDA must include the best price of an authorized generic drug in its computation of best price for a single source or an innovator multiple source drug during a rebate period to any manufacturer, wholesaler, retailer, provider, HMO, non-profit entity, or governmental entity in the United States, only when such drugs are being sold by the manufacturer holding the NDA.

(d) *Inclusion of authorized generic in AMP and best price by a secondary manufacturer.* The secondary manufacturer of an authorized generic drug must provide a rebate based on its sales of authorized generics, and must calculate AMP and best price, consistent with the requirements specified in §§ 447.504 and 447.505.

§ 447.507 Identification of inhalation, infusion, instilled, implanted, or injectable drugs (5i drugs).

(a) *Identification of a 5i drug.* A manufacturer must identify to CMS each covered outpatient drug that qualifies as a 5i drug.

(b) *Not generally dispensed through a retail community pharmacy.* A manufacturer must determine if the 5i drug is not generally dispensed through a retail community pharmacy based on the percentage of sales to entities other than retail community pharmacies.

(1) A 5i drug is not generally dispensed through a retail community pharmacy if 70 percent or more of the sales (based on units at the NDC-9 level) of the 5i drug, were to entities other than retail community pharmacies or wholesalers for drugs distributed to retail community pharmacies.

(2) A manufacturer is responsible for determining and reporting to CMS whether a 5i drug is not generally dispensed through a retail community pharmacy on a monthly basis.

§ 447.508 Exclusion from best price of certain sales at a nominal price.

(a) *Exclusion from best price.* Sales of covered outpatient drugs by a manufacturer at nominal prices are

excluded from best price when purchased by the following entities:

(1) A covered entity as described in section 340B(a)(4) of the PHSA.

(2) An ICF/IID providing services as set forth in § 440.150 of this chapter.

(3) A State-owned or operated nursing facility providing services as set forth in § 440.155 of this chapter.

(4) A public or non-profit entity, or an entity based at an institution of higher learning whose primary purpose is to provide health care services to students of that institution, that provides family planning services described under section of 1001(a) of PHSA, 42 U.S.C. 300.

(5) An entity that:

(i) Is described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of that Act or is State-owned or operated; and

(ii) Is providing the same services to the same type of population as a covered entity described in section 340B(a)(4) of the PHSA but does not receive funding under a provision of law referred to in such section.

(b) *Nonapplication.* This restriction does not apply to sales by a manufacturer of covered outpatient drugs that are sold under a master agreement under 38 U.S.C. 8126.

(c) *Rule of construction.* Nothing in this section is construed to alter any existing statutory or regulatory prohibition on services for an entity described paragraph (a)(5) of this section, including the prohibition set forth in section 1008 of the PHSA.

§ 447.509 Medicaid drug rebates (MDR).

(a) *Determination of rebate amount—*

(1) *Basic rebate for single source drugs and innovator multiple source drugs.*

The amount of basic rebate for each dosage form and strength of a single source drug or an innovator multiple source drug is equal to the product of:

(i) The total number of units of each dosage form and strength paid for under the State plan in the rebate period (as reported by the State); and

(ii) The greater of:

(A) The difference between the AMP and the best price for the dosage form and strength of the drug; or

(B) The AMP for the dosage form and strength of the drug multiplied by one of the following percentages:

(1) For a clotting factor, 17.1 percent;

(2) For a drug approved by FDA exclusively for pediatric indications, 17.1 percent; or

(3) For all other single source drugs and innovator multiple source drugs, 23.1 percent.

(2) *Additional rebate for single source and innovator multiple source drugs.* In

addition to the basic rebate described in paragraph (a)(1) of this section, for each dosage form and strength of a single source drug or an innovator multiple source drug, the rebate amount will be increased by an amount equal to the product of the following:

(i) The total number of units of such dosage form and strength paid for under the State plan in the rebate period.

(ii) The amount, if any, by which:

(A) The AMP for the dosage form and strength of the drug for the period exceeds:

(B) The base date AMP for such dosage form and strength, increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index associated with the base date AMP of the drug.

(3) *Total rebate.* The total rebate amount for single source drugs and innovator multiple source drugs is equal to the basic rebate amount plus the additional rebate amount, if any.

(4) *Treatment of new formulations.* (i) In the case of a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form, the rebate obligation is the amount computed under paragraphs (a)(1) through (3) of this section for such new drug or, if greater, the product of all of the following:

(A) The AMP of the line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form.

(B) The highest additional rebate (calculated as a percentage of AMP) under this section for any strength of the original single source drug or innovator multiple source drug.

(C) The total number of units of each dosage form and strength of the line extension product paid for under the State plan in the rebate period (as reported by the State).

(ii) The alternative rebate is required to be calculated if the manufacturer of the line extension drug also manufactures the initial brand name listed drug or has a corporate relationship with the manufacturer of the initial brand name listed drug.

(5) *Limit on rebate.* In no case will the total rebate amount exceed 100 percent of the AMP of the drug.

(6) *Rebate for noninnovator multiple source drugs.* The amount of the rebate for each dosage form and strength of a noninnovator multiple source drug will be equal to the product of:

(i) The total number of units of such dosage form and strength for which

payment was made under the State plan for the rebate period; and

(ii) The AMP for the dosage form and strength for the rebate period multiplied by 13 percent.

(b) *Rebates for drugs dispensed through Medicaid managed care organizations (MCOs).* (1) Manufacturers participating in the Medicaid drug rebate program will provide a rebate for covered outpatient drugs dispensed to individuals enrolled in Medicaid MCOs if the MCO is contractually required to provide such drugs.

(2) Manufacturers are exempt from the requirement in paragraph (b)(1) of this section if such drugs are the following:

(i) Dispensed by health maintenance organizations including MCOs that contract under section 1903(m) of the Act; and

(ii) Discounted under section 340B of the PHSA.

(c) *Federal offset of rebates.* States must remit to the Federal government the amount of the savings resulting from the following increases in the rebate percentages.

(1) For single source or innovator multiple source drugs other than blood clotting factors and drugs approved by FDA exclusively for pediatric indications:

(i) If AMP minus best price is less than or equal to AMP times 15.1 percent, then the offset amount is the full 8.0 percent of AMP (the difference between 23.1 percent of AMP and 15.1 percent of AMP).

(ii) If AMP minus best price is greater than AMP times 15.1 percent but less than AMP times 23.1 percent, then the offset amount is the difference between AMP times 23.1 percent and AMP minus best price.

(iii) If AMP minus best price is equal to or greater than AMP times 23.1 percent, then there is no offset amount.

(2) For single source or innovator multiple source drugs that are clotting factors and drugs approved by FDA exclusively for pediatric indications that are subject to a rebate percentage of 17.1 percent of AMP:

(i) If AMP minus best price is less than or equal to AMP times 15.1 percent, then the offset amount is the full 2.0 percent of AMP (the difference between 17.1 percent of AMP and 15.1 percent of AMP).

(ii) If AMP minus best price is greater than AMP times 15.1 percent but less than AMP times 17.1 percent, then the offset amount is the difference between AMP times 17.1 percent and AMP minus best price.

(iii) If AMP minus best price is equal to or greater than AMP times 17.1 percent, then there is no offset amount.

(3) For a drug that is a line extension of a single source or innovator multiple source drug that is an oral solid dosage form, the offset amount is the difference between the unit rebate amount (URA) calculation for the drug calculated based on the applicable rebate percentage in section 1927 of the Act prior to the Affordable Care Act and the calculation of the URA for the line extension drug, if greater, in accordance with the Affordable Care Act.

(4) For noninnovator multiple source drugs, the offset amount is equal to 2.0 percent of the AMP (the difference between 13.0 percent of AMP and 11.0 percent of AMP).

§ 447.510 Requirements for manufacturers.

(a) *Quarterly reports.* A manufacturer must report product and pricing information for covered outpatient drugs to CMS not later than 30 days after the end of the rebate period. The quarterly pricing report must include the following:

(1) AMP, calculated in accordance with § 447.504.

(2) Best price, calculated in accordance with § 447.505.

(3) Customary prompt pay discounts, which are reported as an aggregate dollar amount for each covered outpatient drug at the nine-digit NDC level, provided to all wholesalers in the rebate period.

(4) Prices that fall within the nominal price exclusion, which are reported as an aggregate dollar amount and include all sales of single source and innovator multiple source drugs to the entities listed in § 447.508(a) for the rebate period.

(b) *Reporting revised quarterly AMP, best price, customary prompt pay discounts, or nominal prices.* (1) A manufacturer must report to CMS any revision to AMP, best price, customary prompt pay discounts, or nominal prices for a period not to exceed 12 quarters from the quarter in which the data were due. Any revision request that exceeds 12 quarters will not be considered, except for the following reasons:

(i) The change is a result of the drug category change or a market date change.

(ii) The change is an initial submission for a product.

(iii) The change is due to termination of a manufacturer from the MDR program for failure to submit pricing data and must submit pricing data to reenter the program.

(iv) The change is due to a technical correction; that is, not based on any

changes in sales transactions or pricing adjustments from such transactions.

(v) The change is to address specific rebate adjustments to States by manufacturers, as required by CMS or court order, or under an internal investigation, or an OIG or Department of Justice (DOJ) investigation.

(2) A manufacturer must report revised AMP within the 12-quarter time period, except when the revision would be solely as a result of data pertaining to lagged price concessions.

(c) *Base date AMP report—(1) Reporting period.* A manufacturer may report a revised Deficit Reduction Act (DRA) base date AMP to CMS within the first 4 full calendar quarters following July 17, 2007.

(2) *Recalculation of the DRA base date AMP.* (i) A manufacturer's recalculation of the DRA base date AMP must only reflect the revisions to AMP as provided for in § 447.504 in effect from October 1, 2007 to December 14, 2010.

(ii) A manufacturer may choose to recalculate the DRA base date AMP on a product-by-product basis.

(iii) A manufacturer must use actual and verifiable pricing records in recalculating the DRA base date AMP.

(3) *Reporting a revised Affordable Care Act base date AMP.* A manufacturer may report a revised Affordable Care Act base date AMP to CMS within the first 4 full calendar quarters following April 1, 2016.

(4) *Recalculation of the Affordable Care Act base date AMP.* (i) A manufacturer's recalculation of the Affordable Care Act base date AMP must only reflect the revisions to AMP as provided for in § 447.504.

(ii) A manufacturer may choose to recalculate the Affordable Care Act base date AMP on a product-by-product basis.

(iii) A manufacturer must use actual and verifiable pricing records in recalculating the Affordable Care Act base date AMP.

(d) *Monthly AMP—(1) Definition.* Monthly AMP means the AMP that is calculated on a monthly basis. A manufacturer must submit a monthly AMP to CMS not later than 30 days after the last day of each prior month.

(2) *Calculation of monthly AMP.* Monthly AMP is calculated based on § 447.504, except the period covered is based on monthly, as opposed to quarterly, sales.

(i) The monthly AMP is calculated based on the weighted average of prices for all the manufacturer's package sizes of each covered outpatient drug sold by the manufacturer during a month.

(ii) It is calculated as net sales divided by number of units sold, excluding goods or any other items specifically excluded in the statute or regulations. Monthly AMP is calculated based on the best data available to the manufacturer at the time of submission.

(iii) In calculating monthly AMP, a manufacturer must estimate the impact of its lagged AMP-eligible price concessions using a 12-month rolling percentage in accordance with the methodology described in this paragraph (d)(2).

(A) For each NDC-9 with at least 12 months of AMP-eligible sales, after adjusting for sales excluded from AMP, the manufacturer calculates a percentage equal to the sum of the price concessions for the most recent 12-month period (inclusive of the current reporting period) available associated with sales subject to the AMP reporting requirement divided by the total in dollars for the sales subject to the AMP reporting requirement for the same 12-month period.

(B) For each NDC-9 with less than 12 months of AMP-eligible sales, the calculation described in paragraph (d)(2)(iii)(A) of this section is performed for the time period equaling the total number of months of AMP-eligible sales.

(iv) The manufacturer multiplies the applicable percentage described in paragraph (d)(2)(iii)(A) or (B) of this section by the total in dollars for the sales subject to the AMP reporting requirement (after adjusting for sales excluded from AMP) for the month being submitted. The result of this multiplication is then subtracted from the total in dollars for the sales subject to the AMP reporting requirement (after adjusting for sales excluded from AMP) for the month being submitted.

(v) The manufacturer uses the result of the calculation described in paragraph (d)(2)(iv) of this section as the numerator and the number of units sold in the month (after adjusting for sales excluded from AMP) as the denominator to calculate the manufacturer's AMP for the NDC for the month being submitted.

(vi) *Example.* After adjusting for sales excluded from AMP, the total lagged price concessions over the most recent 12-month period available associated with sales for NDC 12345-6789 subject to the AMP reporting requirement equal \$200,000, and the total in dollars for the sales subject to the AMP reporting requirement for the same period equals \$600,000. The lagged price concessions percentage for this period equals $200,000/600,000 = 0.33333$. The total in dollars for the sales subject to the AMP

reporting requirement for the month being reported equals \$50,000 for 10,000 units sold. The manufacturer's AMP calculation for this NDC for this month is: $\$50,000 - (0.33333 \times \$50,000) = \$33,334$ (net total sales amount); $\$33,334/10,000 = \3.33340 (AMP).

(3) *Timeframe for reporting revised monthly AMP.* A manufacturer must report to CMS revisions to monthly AMP for a period not to exceed 36 months from the month in which the data were due, except as allowed in paragraph (b)(1) of this section.

(4) *Exception.* A manufacturer must report revisions to monthly AMP within the 36-month time period, except when the revision would be solely as a result of data pertaining to lagged price concessions.

(5) *Terminated products.* A manufacturer must not report a monthly AMP for a terminated product beginning with the first month after the expiration date of the last lot sold.

(6) *Monthly AMP units.* A manufacturer must report the total number of units that are used to calculate the monthly AMP in the same unit type as used to compute the AMP to CMS not later than 30 days after the last day of each month.

(e) *Certification of pricing reports.* Each report submitted under paragraphs (a) through (d) of this section must be certified by one of the following:

(1) The manufacturer's chief executive officer (CEO).

(2) The manufacturer's chief financial officer (CFO).

(3) An individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO; or

(4) An individual with the directly delegated authority to perform the certification on behalf of an individual described in paragraphs (e)(1) through (3) of this section.

(f) *Recordkeeping requirements.* (1) A manufacturer must retain records (written or electronic) for 10 years from the date the manufacturer reports data to CMS for that rebate period.

(i) The records must include these data and any other materials from which the calculations of the AMP, the best price, customary prompt pay discounts, and nominal prices are derived, including a record of any assumptions made in the calculations.

(ii) The 10-year timeframe applies to a manufacturer's quarterly and monthly submissions of pricing data, as well as any revised pricing data subsequently submitted to CMS.

(2) A manufacturer must retain records beyond the 10-year period if all of the following circumstances exist:

(i) The records are the subject of an audit, or of a government investigation related to pricing data that are used in AMP, best price, customary prompt pay discounts, or nominal prices of which the manufacturer is aware.

(ii) The audit findings or investigation related to the AMP, best price, customary prompt pay discounts, or nominal price have not been resolved.

(g) *Data reporting format.* All product and pricing data, whether submitted on a quarterly or monthly basis, must be submitted to CMS in an electronic format designated by CMS.

§ 447.511 Requirements for States.

(a) *Invoices submitted to participating drug manufacturers.* Within 60 days of the end of each quarter, the State must bill participating drug manufacturers an invoice which includes, at a minimum, all of the following data:

- (1) The State code.
- (2) National Drug Code.
- (3) Period covered.
- (4) Product FDA list name.
- (5) Unit rebate amount.
- (6) Units reimbursed.
- (7) Rebate amount claimed.
- (8) Number of prescriptions.
- (9) Medicaid amount reimbursed.
- (10) Non-Medicaid amount

reimbursed.

(11) Total amount reimbursed.

(b) *Data submitted to CMS.* On a quarterly basis, the State must submit drug utilization data to CMS, which will be the same information as submitted to the manufacturers.

(c) *State that has participating Medicaid Managed care organizations (MCO).* A State that has participating Medicaid managed care organizations (MCO) which includes covered outpatient drugs in its contracts with the MCOs, must report data described in paragraph (a) of this section for covered outpatient drugs dispensed to individuals eligible for medical assistance who are enrolled with the MCO and for which the MCO is required under contract for coverage of such drugs under section 1903 of the Act. These data must be identified separately from the data pertaining to drugs that the State reimburses on a fee-for-service basis.

§ 447.512 Drugs: Aggregate upper limits of payment.

(a) *Multiple source drugs.* Except for brand name drugs that are certified in accordance with paragraph (c) of this section, the agency payment for multiple source drugs must not exceed, in the aggregate, the amount that would result from the application of the specific limits established in accordance

with § 447.514. If a specific limit has not been established under § 447.514, then the rule for "other drugs" set forth in paragraph (b) of this section applies.

(b) *Other drugs.* The agency payments for brand name drugs certified in accordance with paragraph (c) of this section and drugs other than multiple source drugs for which a specific limit has been established under § 447.514 must not exceed, in the aggregate, payment levels that the agency has determined by applying the lower of the following:

(1) AAC plus a professional dispensing fee established by the agency; or

(2) Providers' usual and customary charges to the general public.

(c) *Certification of brand name drugs.*

(1) The upper limit for payment for multiple source drugs for which a specific limit has been established under § 447.514 does not apply if a physician certifies in his or her own handwriting (or by an electronic alternative means approved by the Secretary) that a specific brand is medically necessary for a particular beneficiary.

(2) The agency must decide what certification form and procedure are used.

(3) A check off box on a form is not acceptable but a notation like "brand necessary" is allowable.

(4) The agency may allow providers to keep the certification forms if the forms will be available for inspection by the agency or HHS.

§ 447.514 Upper limits for multiple source drugs.

(a) *Establishment and issuance of a listing.* (1) CMS will establish and issue listings that identify and set upper limits for multiple source drugs available for purchase by retail community pharmacies on a nationwide basis that FDA has rated at least three drug products as pharmaceutically and therapeutically equivalent in the "Approved Drug Products with Therapeutic Equivalence Evaluations" which is available at <http://www.accessdata.fda.gov/scripts/cder/ob/>. Only pharmaceutically and therapeutically equivalent formulations will be used to determine such limit, and such limit will only be applied to those equivalent drug products.

(2) CMS publishes the list of multiple source drugs for which upper limits have been established and any revisions to the list in Medicaid Program issuances.

(b) *Specific upper limits.* (1) The agency's payments for multiple source drugs identified and listed periodically

by CMS in Medicaid Program issuances must not exceed, in the aggregate, prior to the application of any federal or state drug rebate considerations, payment levels determined by applying for each pharmaceutically and therapeutically equivalent multiple source drug product, a professional dispensing fee established by the state agency plus an amount established by CMS that is equal to 175 percent of the weighted average of the most recently reported monthly AMPs for such multiple source drugs, using manufacturer submitted utilization data for each multiple source drug for which a Federal upper limit (FUL) is established.

(2) *Exception.* If the amount established by CMS in paragraph (b)(1) of this section for a pharmaceutically and therapeutically equivalent multiple source drug product is lower than the average retail community pharmacies' acquisition cost for such drug product, as determined by the most current national survey of such costs, CMS will use a percent of the weighted average of the most recently reported monthly AMPs that equals the most current average acquisition costs paid by retail community pharmacies as determined by such survey.

(c) *Ensuring a drug is for sale nationally.* To assure that a multiple source drug is for sale nationally, CMS will consider the following additional criteria:

(1) The AMP of a terminated NDC will not be used to set the Federal upper limit (FUL) beginning with the first day of the month after the termination date reported by the manufacturer to CMS.

(2) The monthly AMP units data will be used to calculate the weighted average of monthly AMPs for all multiple source drugs to establish the FUL.

(d) The FUL will be applied as an aggregate upper limit.

§ 447.516 Upper limits for drugs furnished as part of services.

The upper limits for payment for prescribed drugs in this subpart also apply to payment for drugs provided as part of skilled nursing facility services and intermediate care facility services and under prepaid capitation arrangements.

§ 447.518 State plan requirements, findings, and assurances.

(a) *State plan.* (1) The State plan must describe comprehensively the agency's payment methodology for prescription drugs, including the agency's payment methodology for drugs dispensed by all of the following:

(i) A covered entity described in section 1927(a)(5)(B) of the Act.

(ii) A contract pharmacy under contract with a covered entity described in section 1927(a)(5)(B) of the Act.

(iii) An Indian Health Service, tribal and urban Indian pharmacy.

(2) The agency's payment methodology in paragraph (a)(1) of this section must be in accordance with the definition of AAC in § 447.502.

(b) *Findings and assurances.* Upon proposing significant State plan changes in payments for prescription drugs, and at least annually for multiple source drugs and triennially for all other drugs, the agency must make the following findings and assurances:

(1) *Findings.* The agency must make the following separate and distinct findings:

(i) In the aggregate, its Medicaid expenditures for multiple source drugs, identified and listed in accordance with § 447.514(a), are in accordance with the upper limits specified in § 447.514(b).

(ii) In the aggregate, its Medicaid expenditures for all other drugs are in accordance with § 447.512.

(2) *Assurances.* The agency must make assurances satisfactory to CMS that the requirements set forth in §§ 447.512 and 447.514 concerning upper limits and in paragraph (b)(1) of this section concerning agency findings are met.

(c) *Recordkeeping.* The agency must maintain and make available to CMS, upon request, data, mathematical or statistical computations, comparisons, and any other pertinent records to support its findings and assurances.

(d) *Data requirements.* When proposing changes to either the ingredient cost reimbursement or professional dispensing fee reimbursement, States are required to evaluate their proposed changes in accordance with the requirements of this subpart, and States must consider both the ingredient cost reimbursement and the professional dispensing fee reimbursement when proposing such changes to ensure that total reimbursement to the pharmacy provider is in accordance with requirements of section 1902(a)(30)(A) of the Act. States must provide adequate data such as a State or national survey of retail pharmacy providers or other reliable data other than a survey to support any proposed changes to either or both of the components of the reimbursement methodology. States must submit to CMS the proposed change in reimbursement and the supporting data through a State plan amendment through the formal review process.

§ 447.520 Federal Financial Participation (FFP): Conditions relating to physician-administered drugs.

(a) No FFP is available for physician-administered drugs for which a State has not required the submission of claims using codes that identify the drugs sufficiently for the State to bill a manufacturer for rebates.

(1) As of January 1, 2006, a State must require providers to submit claims for single source, physician-administered drugs using Healthcare Common Procedure Coding System codes or NDC numbers to secure rebates.

(2) As of January 1, 2007, a State must require providers to submit claims for physician-administered single source drugs and the 20 multiple source drugs identified by the Secretary using NDC numbers.

(b) As of January 1, 2008, a State must require providers to submit claims for the 20 multiple source physician-administered drugs identified by the Secretary as having the highest dollar value under the Medicaid Program using NDC numbers to secure rebates.

(c) A State that requires additional time to comply with the requirements of this section may apply to the Secretary for an extension.

§ 447.522 Optional coverage of investigational drugs and other drugs not subject to rebate.

(a) Medicaid coverage of investigational drugs may be provided at State option under section 1905(a)(12) of the Act when such drug is the subject of an investigational new drug application (IND) that has been allowed by FDA to proceed.

(b) A State agency electing to provide coverage of an investigational drug must include in its State plan a description of the coverage and payment for such drug.

(c) The State plan must indicate that any reimbursement for investigational drugs by the State are consistent with FDA regulations at 21 CFR part 312 if they are to be eligible to receive FFP for these drugs.

(d) Medicaid coverage of other drugs may be provided at State option under section 1905(a)(12) of the Act provided that they are not eligible to be covered as covered outpatient drugs in the Medicaid Drug Rebate program.

(e) Investigational drugs and other drugs are not subject to the rebate requirements of section 1927 of the Act provided they do not meet the definition of a covered outpatient drug as set forth in section 1927(k) of the Act.

Dated: October 1, 2015.

Andrew M. Slavitt,

*Acting Administrator, Centers for Medicare
& Medicaid Services.*

Dated: November 24, 2015.

Sylvia M. Burwell,

*Secretary, Department of Health and Human
Services.*

[FR Doc. 2016-01274 Filed 1-21-16; 4:15 pm]

BILLING CODE 4120-01-P