This document, Optional Purchasing Specifications: Pharmaceutical Benefits and Services in Medicaid Managed Care, was prepared by The George Washington University Center for Health Services Research and Policy (CHSRP) through an educational grant from GlaxoSmithKline (formerly Glaxo Wellcome Inc.). This document articulates a series of policy options relating to managed care coverage of pharmaceuticals and pharmaceutical services for Medicaid beneficiaries. These options are presented in the form of “sample” purchasing specifications, which could be used in a purchasing or service agreement under which a state Medicaid agency (“Purchaser”) procures comprehensive or specialized health care services from a managed care organization (“Contractor”). A managed care organization (MCO) could also use the specifications as a “Purchaser” of Medicaid pharmaceutical coverage from a subcontractor. The document is designed for use as a technical assistance tool for Purchasers and stakeholders that wish to identify key decision points in purchasing pharmaceutical benefits and services and to articulate policy preferences for Medicaid managed care coverage of this benefit.

These sample purchasing specifications are optional, and do not necessarily reflect the views of the Centers for Medicare & Medicaid Services (CMS, formerly the Health Care Financing Administration, HCFA). The document is not a statement of the sponsor’s, reviewers’ or consultants’ policy or contracting preferences, nor their interpretation of any law or regulation.

Compared with commercial managed care enrollees, Medicaid managed care enrollees are more likely to experience complex, chronic and disabling conditions that are responsive to drug therapies. The broad Federal Medicaid outpatient prescription drug benefit was designed for the special needs of this population and includes important beneficiary protections, limiting a state Medicaid agency’s use of restrictive formularies or prior authorization to hinder beneficiary access to covered drugs.¹

Federal law does not require state Medicaid agencies to include the statutory standards and procedures for prescription drugs (or even a prescription drug benefit) in their Medicaid managed care contracts. However, to the extent that a state’s Medicaid managed care prescription drug coverage is narrower than that required under federal law, the state remains financially liable for residual drug coverage. This document illustrates how to adapt federal statutory standards and procedures for the Medicaid outpatient prescription drug benefit to the typical structure of managed care contracting documents, including requests for proposals and service agreements. A majority of states now choose to incorporate into their managed care contracts at least some elements of the federal standards.

This document is divided into two Parts. Part 1 sets forth the covered pharmaceutical benefits and services, including information required for enrollees and coverage determination standards and procedures. Part 2 contains illustrative language relating to the delivery of pharmaceutical benefits and services. This includes specifications on enrollee access, enrollment and disenrollment, provider network, quality measurement and improvement, data collection and reporting, and information for providers.

The illustrative language in this document is drafted to minimize ambiguity and maximize clarity. The more clearly an MCO understands what is expected of it by the purchaser, and the more clearly a purchaser understands what the MCO is obligating itself to provide, the more likely it is than any agreement between the two parties will be carried out to the mutual satisfaction of each and to the benefit of enrollees with the MCO.

Every state purchaser has its own drafting format. The particular format used in these purchasing specifications is NOT intended as a substitute for each state’s own format. Instead, it is intended simply to divide each suggested provision into the smallest practicable policy elements. This division and subdivision format is designed to enable a user to identify quickly the policy choices contained in each provision and to identify which, if any, of the elements the user wishes to adopt. This format also serves as a detailed checklist for those users who wish to compare portions of their current purchasing documents with the relevant portions of these purchasing specifications.

This document is not designed as a complete contract document, addressing all issues in the purchase of pharmaceutical benefits and services. Because of variations in Purchasers' financing options, policy preferences and legal duties, there is no single correct method for covering and delivering health and medical benefits and services to Medicaid populations, particularly in a benefit as complex as pharmaceuticals and

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pharmaceutical services. The document also does not include broadly applicable "generic" provisions, such as enrollee grievance and appeals procedures and payment provisions.

Process for Developing this Technical Assistance Document

Since 1995, CHSRP has conducted an intensive examination of contracts between state Medicaid agencies and MCOs. This analytic work has produced three editions of a comprehensive study of contract provisions. The most recent version is the five-volume document, Sara Rosenbaum, et al., Negotiating the New Health System: A Nationwide Study of Medicaid Managed Care Contracts, 3rd Ed. (1999), www.gwhealthpolicy.org. The study breaks down the contracts into a series of analytic tables. Coverage of prescription drugs is addressed in the following tables in Negotiating the New Health System: Tables 2.1 (General Services), 2.2 (Substance Abuse and Mental Health Services), and 3.9 (Drug Formularies).

Negotiating the New Health System is part of a broader analytic studies and technical assistance project on managed care contracts financed by numerous funders, including the David and Lucile Packard Foundation, the Centers for Disease Control and Prevention (CDC), the Substance Abuse and Mental Health Services Administration (SAMHSA), and the Health Resources and Services Administration (HRSA). Original funding for this project was supported by Pew Charitable Trusts and the Annie E. Casey Foundation. The development of purchasing specifications for managed care products constitutes one component under this project. Support for development of this document and other elements of a Medicaid pharmaceuticals project was provided through an educational grant to CHSRP from GlaxoSmithKline (formerly Glaxo Wellcome Inc.).

These sample specifications were drafted by CHSRP legal and health care research staff. Drafters worked with consulting pharmacists who are affiliated with pharmaceutical policy centers and the Universities of Maryland and Michigan, and who provide expert consultation to state Medicaid prescription drug programs. The draft specifications were reviewed by the consulting pharmacists, as well as through a series of vetting meetings with expert advisory panels comprised of state Medicaid officials with responsibility for drug coverage in their states and representatives from CMS, the managed care industry, and consumers. The changes suggested through these reviews have been incorporated into the specifications and have been reviewed by representatives from these meetings. The specifications are also available at www.gwhealthpolicy.org.

How to Use this Technical Assistance Document

The drafting format used in these purchasing specifications is as follows:

- Each Part is divided into sections, identified by “§.”
- Each section, in turn, is divided into one or more subsections: “(a),” “(b),” etc.
Commentaries in footnotes identify and discuss relevant provisions in Federal Medicaid law, provide rationales for certain specifications and background information, and, in some instances, suggest alternative options for additional specifications.

The term “pharmaceuticals” is used throughout the document to indicate prescription and other drugs and the range of "non-drug drugs" such as insulin, regulated nutritional products and devices for administering drugs that are covered under the Medicaid outpatient prescription drug benefit.

Italicized notes to “drafter” in the illustrative language indicate areas where a Purchaser may elect to incorporate relevant laws, identify the frequency with which an event (e.g., formulary review) should occur, and other matters. Certain terms used in this document are defined in a separate section (§106).

CHSRP has developed a number of purchasing specifications for specific populations, conditions, or services, which are listed in Table 1 below. Some of these other purchasing specifications address coverage of drugs for the condition or population (e.g., HIV/AIDS or children with special health care needs). However, these pharmaceutical specifications do not address diagnosis-specific pharmaceutical provisions; interested purchasers may review the population-based or condition-specific specifications for additional illustrative language on the coverage of drugs for the population or condition.
## Table 1. Purchasing Specifications
Under Development or Available from CHSRP

The dated specifications are posted on CHSRP’s website, [www.gwhealthpolicy.org](http://www.gwhealthpolicy.org). All other listed specifications are under development.

| Population-Based Specifications                                      |
|-------------------------------------------------|------------------|
| Adults with Behavioral Health Needs (December 2001)             |
| Child Welfare (December 2001)                                 |
| Children with Behavioral Health Needs (October 2000)           |
| Children with Special Health Care Needs (August 2000)           |
| Pediatric Services (Medicaid) (September 1999)                  |
| Pediatric Services (SCHIP)                                    |
| Individuals Who Are Homeless (June 2000)                       |

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<td>Pharmaceutical Benefits and Services (December 2001)</td>
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<td>School-based Health Center Services Reimbursement</td>
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<td>Diabetes (July 2000)</td>
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<td>HIV/AIDS (August 1999)</td>
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<td>User's Guide Relating to Pediatrics</td>
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<td>User's Guide Relating to Public Health Conditions and Services</td>
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### Part 1. Pharmaceutical Benefits

§101. In General
- (a) Applicability of Terms and Conditions
- (b) Applicability of State and Federal Law and Regulation
- (c) Modification of State and Federal Law and Regulation

§102. Benefits and Services
- (a) General Rule

§103. Pharmaceuticals and Pharmaceutical Services
- (a) Covered Pharmaceuticals
- (b) Covered Pharmaceutical Services
- (c) Pharmaceuticals That Are Not Covered

§104. Information for Enrollees
- (a) General Rule

§105. Coverage Determination Standards and Procedures
- (a) Medical Necessity
- (b) Procedures for Use of Formularies and Prior Authorization of Pharmaceuticals
- (c) Continuity of Pharmaceutical Therapy

§106. Definitions
- (a) General Rule

### Part 2. Service Delivery and Health Care Quality Measurement and Improvement

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§206. Information for Providers
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Part 1. Pharmaceutical Benefits

§101. In General
§102. Benefits and Services
§103. Pharmaceuticals and Pharmaceutical Services
§104. Information for Enrollees
§105. Coverage Determination Standards and Procedures
§106. Definitions

§101. In General

(a) Applicability of Terms and Conditions — The terms and conditions of this Agreement shall apply to Contractor and to any subcontractor or other person or entity to which Contractor delegates any of its duties under the Agreement.

(b) Applicability of State and Federal Law and Regulation — In carrying out the terms and conditions of this Agreement, Contractor shall comply with:

(1) [drafter insert references to state and federal law, regulation and guidance on privacy of medical, pharmacy or other types of records that contain information that could be used to identify an enrollee to whom pharmaceuticals covered under the Agreement are prescribed, dispensed or administered];

(2) [drafter insert reference to state pharmacy practice law and regulation];

(3) [to the extent that Purchaser elects to make state and federal Medicaid law or state Medicaid drug coverage policies directly applicable to Contractor, drafter insert reference to state Medicaid plan and/or policies for coverage of pharmaceuticals and pharmaceutical services and/or applicable federal Medicaid law, regulation and/or guidance];

Commentary: Multiple state and federal statutes and regulations are applicable to activities described in these sample specifications. This subsection is provided for a Purchaser that wishes to incorporate such laws and regulations, in part or in whole, into its purchasing specifications relating to pharmaceuticals and pharmaceutical services. Modifications of individual specifications elsewhere in this document also may be needed to conform with state law.

Commentary: Drafter may wish to clarify with the state pharmacy practice board the portions of the state’s practice law, regulations and/or board opinions that may be relevant to coverage of pharmaceuticals and pharmaceutical services under this Agreement.

Commentary: This language is provided for a Purchaser that wishes a Contractor to comply with such standards and policies of the state’s Medicaid program as are selected by the Purchaser and to make such standards and policies generally applicable throughout an Agreement relating to pharmaceutical and pharmaceutical services benefits. Another option would be to incorporate specific components of a state’s pharmaceutical coverage policies, such as coverage of non-prescription drugs, within sections that address relevant topics. Examples of the second option are provided at several places in this document.
(4) [drafter insert references to other state or federal law, regulation or agency guidance that pertains to the performance of Contractor’s duties under the Agreement].

(c) **Modification of State and Federal Law and Regulation** — Effective after [drafter insert period of time after which this provision is effective], Contractor shall comply with any modification of state or federal law, regulation, agency guidance or policy described in subsection (b)(1)-(4), unless Contractor and Purchaser agree otherwise in writing, provided that:

(1) Contractor has received notice of the modification from Purchaser [drafter insert period of time] before the effective date of the modification; or

(2) in the case that Contractor does not receive timely notice of the modification from Purchaser under paragraph (1), such modification shall be effective after [drafter insert period of time after which this provision is effective] of Contractor’s receipt of notice of the modification.

§102. **Benefits and Services**

(a) **General Rule** — Contractor shall, for each enrollee, cover and furnish, or arrange for the furnishing of, the pharmaceuticals and pharmaceutical services enumerated in §103 in accordance with the standards and procedures relating to:

(1) information for enrollees as described in §104;

(2) coverage determination standards and procedures as described in §105;

(3) supply of pharmaceuticals for prevention or treatment of sexually transmitted diseases to clinical provider sites as described in §201(a);

(4) safeguards against interruption of pharmaceutical therapy as described in §202(a); and

(5) the drug use review standards and procedures as described in §204(a).

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7 **Commentary:** This provision is drafted to permit the updating of an Agreement after it goes into effect by incorporating any change(s) (“modifications”) in state or federal laws or other materials that are part of the Agreement (“incorporated”) under subsection (b) of this section. A delayed effective date (e.g., 60 days or 90 days) would permit (1) notice to enrollees of any reduction or increase in covered benefits; and (2) negotiation, if necessary, of modified rates of payment consistent with a decrease or increase of Contractor’s financial liability resulting from a change in relevant laws of policies.
§103. Pharmaceuticals and Pharmaceutical Services

(a) Covered Pharmaceuticals — Pharmaceuticals covered under this Agreement are drugs and other pharmaceutical products that are:

(1) prescribed drugs approved under §§505, 505(j), or 507 of the Federal Food, Drug and Cosmetic Act (FDCA) that are:

Commentary: This subsection sets out the definition and scope of the optional Medicaid outpatient drug benefit, as set out in federal law, §§1902(a)(10)(i),(ii), 1902(a)(54), 1903(i)(10), 1905(a)(12), 1927(a),(d),(k)(2),(3),(g)(1)(B)(i) of the Social Security Act, 42 U.S.C. §§1396a(a)(10)(i),(ii), 1396a(a)(54), 1396b(i)(10), 1396d(a)(12), 1396r-8(a),(d),(k)(2),(3),(g)(1)(B)(i). Outpatient prescription drug coverage is an optional Medicaid benefit that all states covered at the time these specifications were drafted. Coverage of pharmaceuticals that are “medically necessary” for a Medicaid beneficiary under age 21 is mandatory; see discussion infra at Commentary 36. This subsection also provides the option of incorporating a state’s Medicaid plan with regard to coverage of, for example, over-the-counter drugs that are eligible for federal matching funds. States electing to cover prescription drugs must provide coverage as set out in this subsection (with the exception of certain vaccines, as noted below). If a Medicaid managed care contract provides for less than the full scope of this coverage, the state Medicaid agency is financially responsible for drugs not provided under the contract. Conversely, a Medicaid managed care contract could require coverage of certain drugs that may not be eligible for federal Medicaid matching funds but that must, under state law, be covered by insurers doing business in the state (e.g., certain investigational drugs, as approved through special state procedures). Such drugs could be fully financed with state funds. For current information on coverage of specific drugs under Medicaid, see the web site of the Medicaid drug rebate program,

www.hcfa.gov/medicaid/drugs/drugmph.htm See also letters to state Medicaid directors relating to drug coverage at www.hcfa.gov/medicaid/drugs and relevant entries in the HCFA State Medicaid Manual, available at www.hcfa.gov/medicaid, and/or consult with Drug Rebate Program officials. (At the time these specifications were drafted the web site addresses are expected to change to reflect the agency name change to CMS. Also, because specific elements of a web site address may change, the general agency web site may be consulted; search the HCFA/CMS web site for “drug rebate program.”)

An alternative description of a pharmaceutical benefit would be: a drug or biological product described in 42 C.F.R. §440.120(a) or §1927(k)(2) of the Social Security Act, 42 U.S.C. §1396r-8(k)(2), and prescribed for an enrollee by a provider who participates in Contractor’s provider network or through which Contractor has otherwise arranged for the furnishing of products or services. The regulatory definition of a prescribed outpatient drug is shown infra at §106(a)(7).

Commentary: 21 U.S.C. §§355, 355(j). 357. In general, approval of a new drug under FDCA requires completion of three-stage clinical trials, demonstrating a drug’s safety and efficacy for an intended use (“indication”). Under two accelerated procedures set out in federal regulation, a drug for treatment of grave, life-threatening illnesses may be approved before completion of such trials. Federal regulations interpret the “safety and effectiveness” standard as a balance of expected benefits and a new drug’s risks “in light of the severity of the disease being treated” and willingness of “physicians and patients to accept greater risks or side effects, than they would accept from products that treat less serious illnesses.” 21 C.F.R. §312.80. Under one procedure, a drug manufacturer may apply for a “treatment new drug application” for a drug that appears promising after completion of the second of three phases of clinical trials. Only new drugs for “serious or immediately life-threatening disorders” for which there is no other “comparable” or “satisfactory” alternative drug for the stage of the patient’s illness, may receive this type of approval. Approval is for use of the drug by individuals with a disorder who cannot participate in its clinical trials (e.g., excluded from trial because of co-existing conditions). 21 C.F.R. §312.80 et seq. The second special procedure is reserved for drugs for AIDS and HIV-related disorders. This procedure permits approval on the basis of “surrogate endpoints” before completion of clinical trials. 21 C.F.R. §314.500 et seq. Under both expedited approval procedures, special conditions such as restricted prescribing authority and post-approval completion of clinical trials may be required. At least one drug, Serostim™, approved under such a procedure, is covered as a Medicaid outpatient prescription drug for
(A) subject to a Medicaid rebate purchase agreement (or alternative pricing arrangement) under Federal law;\textsuperscript{11} and

(B) prescribed for a medical indication that is:\textsuperscript{12}

   (i) the indication for which the drug was approved under FDCA; or

   (ii) a use supported by one or more citations included or approved for inclusion in at least one of the following compendia:

   (I) American Hospital Formulary Service Drug Information;

   (II) United States Pharmacopeia-Drug Information;

   (III) the DRUGDEX Information System; or

   (IV) American Medical Association Drug Evaluations;

   (2) prescription biological products other than vaccines that are licensed under and produced in an establishment licensed under §351 of the Public Health Service Act;

   (3) insulin certified under §506 of the FDCA;

   (4) vaccines other than those described in subsection (c)(1);\textsuperscript{13}

\textsuperscript{11} At the time the specifications were drafted, virtually all FDA-approved drugs and pharmaceuticals were covered by such contracts or alternate pricing arrangements. See Sara Rosenbaum, et al., Negotiating the New Health System: A Nationwide Study of Medicaid Managed Care Contracts, 3rd Ed. (1999), Vol. 2., Pt. 2, Tables 2.1 and 2.2, GWU Center for Health Services Research and Policy, www.gwhealthpolicy.org.

\textsuperscript{12} Commentary: This paragraph sets out the statutory definition of “medically accepted indication.” as either a use for which a drug is “labeled” by the Food and Drug Administration (approved for marketing) or an “off-label” use published in national compendia of drug use and research reports (including peer-reviewed literature). §1927(k)(6), (g)(1)(B)(i) of the Social Security Act, 42 U.S.C. §1396r-8(k)(6), (g)(1)(B)(i). (At the time these specifications were drafted, one compendium, American Medical Association Drug Evaluations, was not being published.) One court that has considered the issue of Medicaid coverage for an “off-label” drug use enjoined a state Medicaid agency from refusing to cover an HIV drug prescribed for a specific indication in accordance with accepted medical practice but not yet approved for that indication under the FDCA. Reagan v. Weaver, 886 F.2d.194 (8th Cir., 1989).

\textsuperscript{13} Commentary: This specification would obligate the Contractor to supply vaccines that are indicated for an enrollee other than those for which an enrolled child or adolescent qualifies under the Federal Vaccines for Children (VFC) program. §1928 of the Social Security Act, 42 U.S.C. §1396s. The specification assumes participation in VFC by network providers serving infants, children and adolescents. Vaccines for adults are not a mandatory element of Medicaid outpatient drug coverage but may be covered under the
(5) nonprescription drugs and biologicals that are covered under [drafter insert reference to state Medicaid plan] prescribed by a network provider;\textsuperscript{14}

(6) prenatal vitamins, fluoride supplements [drafter insert reference to coverage of other vitamins and minerals in the state Medicaid plan] prescribed by a network provider;\textsuperscript{15}

(7) nutritional products and dietary supplements that are covered under [drafter insert reference to state Medicaid plan] prescribed by a network provider;\textsuperscript{16}

(8) pharmaceutical devices and supplies, which shall include:

(A) devices that are required to administer covered pharmaceuticals;

(B) condoms (male and female);\textsuperscript{17} and

(C) [drafter insert citation to any state law requiring coverage of specific pharmaceutical devices and supplies];\textsuperscript{18} and

optional Medicaid preventive services benefit. §1905(a)(13) of the Social Security Act, 42 U.S.C. §1396d(a)(13). Immunizations for adults at risk of certain conditions (e.g., pneumococcal pneumonia) are recommended by public health experts. See the Centers for Disease Control and Prevention, Recommendations of the Advisory Committee on Immunization Practices, list of Comprehensive Recommendations, \url{www.cdc.gov/nip/publications/ACIP-list.htm}

Because vaccines may be covered as part of a “medical” (as opposed to a “pharmaceutical”) benefit under a comprehensive Agreement that includes pharmaceutical coverage, interested purchasers may wish to clarify Contractor’s responsibility to supply vaccines other than those distributed under the VFC program.\textsuperscript{14} \underline{Commentary}: A state Medicaid agency may elect to cover non-prescription drugs or selected non-prescription drugs if prescribed for a beneficiary. §1927(d)(2)(G) of the Social Security Act, 42 U.S.C. §1396r-8(d)(2)(G). Drafter may wish to list specific covered non-prescription drugs or to provide such a listing in an appendix to the Agreement.

\textsuperscript{15} \underline{Commentary}: A state Medicaid agency must cover prenatal vitamins and fluoride supplements and may elect to cover other vitamins and minerals. §1927(d)(2)(F) of the Social Security Act, 42 U.S.C. §1396r-8(d)(2)(F). Drafter may wish to list specific covered vitamins and minerals or to provide such a listing in an appendix to the Agreement.

\textsuperscript{16} \underline{Commentary} A state Medicaid agency may elect to cover “agents” for treating anorexia, weight loss or weight gain; under HCFA guidance, coverage of certain nutritional products or dietary supplements may be considered a “medically indicated” use (e.g., treatment of wasting in AIDS patients) that must be covered. Drafter may wish to list specific covered nutritional products and dietary supplements or to provide such a listing in an appendix to the Agreement.

\textsuperscript{17} \underline{Commentary} Coverage of condoms is not specifically required under federal Medicaid law, except that certain condoms (e.g., those containing spermicidal agents) may be considered covered drugs under HCFA guidance, see \textit{supra, Commentary 8}. Promoting condom use is considered a critical public health measure to interrupt the transmission of sexually transmitted diseases (STD) and HIV and to prevent unintended pregnancy. Centers for Disease Control and Prevention, 1998 Guidelines for Treatment of Sexually Transmitted Diseases, \textit{MMWR} 1998; 47 (No. RR-1), \url{www.cdc.nchstp/dstd/1998_guidelines_for_the_treatment.htm} Making condoms available on request and without a prescription at certain health care sites (e.g., family planning services, obstetrical/gynecological services) is considered by public health experts to be an important step in promoting condom use.
(9) other pharmaceutical products that are covered under [drafter insert reference to state Medicaid plan].^{19,20}

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^{18} **Commentary:** For example, certain state laws regulating health insurers (including managed care organizations) require coverage of diabetes self-monitoring equipment, lancets, test strips and other items prescribed for diabetes self-management.

^{19} **Commentary:** Such products include anti-hemophilic factors, self-administered injectable products and other products not otherwise described in this subsection that are covered under the state Medicaid plan. Drafter may wish to list such products specifically or to provide such a listing in an appendix to the Agreement.

^{20} **Commentary:** This commentary provides an additional sample specification, for drafters who wish to address coverage of pharmaceuticals in special circumstances. Purchasers electing to use this specification may wish to review current HCFA reimbursement policies to determine availability of federal matching funds, *supra, Commentary 8*. This sample specification is designed for circumstances in which inherent characteristics of subsets of Medicaid beneficiaries (i.e., age or diagnosis) could effectively restrict their access to needed pharmaceuticals compared with that of other Medicaid beneficiaries of differing ages or with different diagnoses. Medical discrimination in coverage, based on a beneficiary’s condition, is prohibited under federal Medicaid regulations. 42 C.F.R. §440.230(c). At least some pharmaceuticals that would be covered under the following sample specification would have qualified for federal matching funds before Medicaid law was amended in the Omnibus Budget Reconciliation Act of 1993. (Prior to the amendment, the scope of drug coverage would have included off-label uses supported by peer-reviewed scientific literature. Support in the literature is now referenced in the statute only in connection with drug use review, see *infra, §204(a)*).

Paragraph (1) of the following sample specification is drafted to support appropriate access for children and adolescents for drugs that are approved for adult uses but that at the time of prescribing were neither labeled for pediatric use nor supported by a compendium report. The Food and Drug Administration has repeatedly noted widespread pediatric prescribing of drugs labeled only for adult uses, and has sought to remedy major deficiencies in pediatric drug labeling. These deficiencies result from ethical and legal restrictions on clinical research in children and acknowledged economic disincentives for clinical drug trials in infants, children and adolescents. Among the major classes of drugs that had not been labeled for pediatric uses at the time these specifications were drafted were: steroids, antidepressants, antihypertensives, antirheumatics, prescription pain medications, drugs to treat gastrointestinal problems and ulcerative colitis, and more than half the drugs that had been approved for treatment of HIV, AIDS and opportunistic infections in adults. 62 Fed. Reg. 43900 (1997), codified 42 CFR Parts 201, 312, 314,601.

Paragraph (2) of the sample specification is drafted to support appropriate access to pharmaceutical therapies (or combinations of therapies) that may not have received final approval for marketing under the Act but which a network physician, experienced in the treatment of an enrollee’s medical condition, considers to be “medically necessary” under criteria set out elsewhere in this document. Examples would include innovative treatments for cancer, coverage of which may also be addressed under state insurance law.

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**Additional Covered Pharmaceuticals** — Additional pharmaceuticals covered under this Agreement are pharmaceuticals that are approved under the FDCA that are not otherwise described in subsection (a)(1) and that are:

1. prescribed for a pediatric (including adolescent) use, provided that:
   
   (A) the use is generally accepted among pediatricians including pediatric specialist and subspecialist physicians and specialists in adolescent medicine; and
   
   (B) in the case of pharmaceuticals prescribed for purposes of contraception, the use is generally accepted among publicly-assisted providers that offer family planning services;

2. prescribed for a use that is determined to be medically necessary in accordance with coverage determination standards at §105 by a health care professional who is trained and experienced in
(b) Covered Pharmaceutical Services — Pharmaceutical services covered under this Agreement are:

(1) enrollee counseling,\textsuperscript{21} which shall:

(A) use standards developed by Contractor's drug use review (DUR) program under §204(a)(3)(C);

(B) be offered to an enrollee by a pharmacist at the time the enrollee presents a prescription for a covered pharmaceutical;

(C) address matters that, in the professional judgment of the pharmacist (and consistent with [draft insert reference to applicable state law]) are significant and that include:\textsuperscript{22}

(i) the name and description of the medication;

(ii) the dosage, dosage form, route of administration, and duration of the enrollee’s drug therapy;

(iii) special directions and precautions for preparation, administration and use of the medication by the enrollee;

(iv) common and severe side or adverse effects or interactions associated with the medication or therapeutic contraindications that may be encountered, how to avoid such problems and what action to take if they occur;

(v) the potential for interactions of herbal or other alternative remedies with the medication;

(vi) techniques for the enrollee to monitor his or her drug therapy;

the treatment and medical management of the illness or condition for which the pharmaceutical is prescribed.

\textsuperscript{21} Commentary: Under federal Medicaid law, states offering outpatient prescription drug coverage must establish drug use review (DUR) programs that include, among other activities, patient counseling as set out in this subsection. §1927(g)(2)(A)(ii) of the Social Security Act, 42 U.S.C. §1396r-8(g)(2)(A)(ii). See §204(a) for other components of a Contractor’s drug use review program. Topics in this specification are those required in federal law except as indicated.

\textsuperscript{22} Commentary: At the time these specifications were drafted, this issue was not addressed in federal Medicaid law but increased use of unregulated “alternative” remedies and early data on adverse interactions with regulated drugs were causing concern among pharmaceutical and medical experts. For example, the Food and Drug Administration asked “health care professionals” to “caution patients about potentially significant interactions between [St. John’s wort] and certain drugs metabolized through the same pathway, which include other protease inhibitors, drugs used to prevent transplant rejection and drugs used to treat heart disease, depression, seizures, and certain cancers.” J.E. Henney, “From the Food and Drug Administration: The Risk of Drug Interactions with St. John’s Wort.” JAMA. 2000; 283:1679.
(vii) proper storage of the medication;

(viii) appropriate action if an enrollee misses or delays a prescribed dose;

(ix) prescription refill information;

(x) pharmacist comments relevant to the individual’s drug therapy; and

(xi) the following topics:

(I) proper use of devices for self-administration of injectables and other covered devices and supplies;

(II) the importance of dates after which a medication is not considered effective and should be discarded; and

(III) appropriate action if another person accidentally takes the medication prescribed for the enrollee; and

(2) [drafter insert one or more other type(s) of other pharmacist services as permitted under state professional practice law].

(c) Pharmaceuticals That Are Not Covered — Pharmaceuticals that are not covered under this Agreement are:

(1) in the case of an enrollee who is eligible for vaccines distributed under the federal Vaccines for Children program, vaccines that are available through the program at the time that immunization with a specific vaccine(s) is indicated for the enrollee;

(2) pharmaceuticals that are excluded from coverage under federal Medicaid law as “less than effective;”

23 Commentary: At the time these specifications were drafted, these issues were not addressed in federal Medicaid law but were identified by reviewers of the specifications as important to consumers.

24 Commentary: Professional practice laws in some states allow pharmacists under specified circumstances to monitor patient drug therapy, administer immunizations and/or provide other clinical services under “collaborative practice agreements” or “drug therapy management protocols” developed with the treating physician and approved by state pharmacy and medical boards on a case-by-case basis. See e.g., Rev. Code Wash. §18.64.001(11) (defining “practice of pharmacy”); Fla. Stat. §465.003(13) (defining “practice of the profession of pharmacy”); and MF Conlan, “Pharmacist prescribing,” Drug Topics 1977; 141:62.

25 Commentary: Under Federal Medicaid law, federal matching payments to a state’s Medicaid program are not available for a drug for which the FDA has issued a proposed notice to withdraw approval of the
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(if applicable: (3) [drafter identify any pharmaceuticals or classes of pharmaceuticals that are not covered under this Agreement but that are covered by Purchaser, either directly or under a separate managed care arrangement for which an enrollee may also qualify]);

(4) [drafter identify any pharmaceuticals or uses of pharmaceuticals that are not covered under this agreement but that are covered under [drafter insert reference to state Medicaid plan] as permitted under federal law].

§104. Information for Enrollees

(a) General Rule — Contractor shall provide information described in this section to enrollees as follows:

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Commentary: Certain states elect to cover certain types of services (e.g., dental and oral health) or certain populations (e.g., children with special health care needs, individuals with AIDS) under separate specialty (“carve out”) managed care arrangements. To the extent that such arrangements include pharmaceutical benefits, Purchaser may wish to exclude such benefits from coverage under this Service Agreement.

Commentary: Under federal law, a state Medicaid program may exclude from coverage or restrict coverage ten classes and/or uses of pharmaceutical agents, because of their potential for abuse or for other policy reasons. However, a state Medicaid agency may still be required to cover some of these drugs for specific medical indications, such as seizure control or wasting associated with AIDS. See supra, Commentary 8, for sources of HCFA (CMS) policies on coverage of specific drugs. Following is the statutory list of drugs for which coverage may be excluded or restricted: (1) drugs used for anorexia, weight loss or weight gain; (2) drugs when used to promote fertility; (3) drugs when used for cosmetic purposes or hair growth; (4) drugs when used for symptomatic relief of cough and colds; (5) drugs when used to promote smoking cessation; (6) prescription vitamins and minerals, except prenatal vitamins and fluoride preparations; (7) nonprescription drugs; (8) covered outpatient drugs for which the manufacturer seeks to require, as a condition of sale, purchase of associated tests or monitoring services exclusively from the manufacturer or its designee; (9) barbiturates; and (10) benzodiazepines. §1927(d)(2) of the Social Security Act, 42 U.S.C. §1396r-8(d)(2).

Commentary: This section identifies types of information that would enable enrollees better to understand the scope and limitations of their pharmaceutical coverage under the Agreement and related matters. Certain specifications were drafted to be consistent with the Balanced Budget Act of 1997, which requires that enrollees and “potential enrollees” in “managed care entities” (MCEs) established under this Act be provided on request with certain information “in a manner or form that is easily understood.” This information includes “the identity, locations, qualifications, and availability” of participating providers, grievance and appeal procedures, and “all items and services that are available to enrollees” from the MCE. In addition, a state must itself or through the MCE provide information on first, covered benefits and any cost-sharing requirements, to be provided annually and on request to MCE enrollees; and second, information on benefits to which an enrollee may be entitled under a state plan but which are not provided by the MCE, and how to get such benefits, to be provided at the time of or before an individual enrolls in an MCE. §1932(a)(5) of the Social Security Act. 42 U.S.C. §1396u-2(a)(5). For sample specifications on enrollee counseling about an enrollee’s prescription, see §103(b)(1).
(1) the information listed in this paragraph shall be provided to enrollees at
the time of enrollment, at the time of material change(s) in the
information, and upon enrollee request:

(A) the identity of pharmaceuticals or classes of pharmaceuticals
and pharmaceutical services that are covered under §103(a) and
(b);

(if applicable: (B) the identity of pharmaceuticals or classes of
pharmaceuticals described in §103(c) that are not covered under
this Agreement but that Purchaser covers under [drafter insert
reference to State Medicaid plan] and:

(i) covers:

   (I) directly; or

   (II) under a separate managed care arrangement;
   and

(ii) how an enrollee may receive such pharmaceuticals);

(C) the names and locations of providers from which an enrollee
may obtain covered pharmaceuticals and pharmaceutical services,
including providers that dispense pharmaceuticals on a 24-hour, 7-
days a week basis under §203(a)(2);

(D) enrollee rights to appeal any denial, termination, reduction or
other restriction in pharmaceutical coverage and how to make such
appeals through Contractor’s grievance and appeals procedures
and Purchaser’s “fair hearing” procedures;

(E) Contractor’s duty under §105(b)(2) with regard to response
time for a prior authorization request, written explanation of

29 Commentary: This information could be provided in enrollee handbooks, by primary care provider
staff, by ombudsman or enrollee assistance programs, or by other means. If Purchaser contracts separately
with an enrollment broker, Purchaser and Contractor may agree that Contractor will supply the required
information for dissemination by the enrollment broker. In considering how information is provided to
enrollees, the difficulties of many low income families in accessing telephone service (and thus,
ombudsman or enrollee assistance programs) or information posted at an Internet site may be balanced with
the burden on Contractors of providing printed materials for enrollees to keep and examine. One option
might be for Contractor to provide printed copies of the information at specified periods and provide
updated information, between such periods, by telephone hotline, availability of information at
participating pharmacies or other means.

30 Commentary: This specification is intended to reference such grievance and appeals procedures as are
included in a comprehensive Medicaid managed care plan that includes these pharmaceutical benefits.
Because these procedures are not specific to pharmaceuticals, they are not addressed in this document.
denial, and provision of emergency supply of a prescribed pharmaceutical;

(F) Contractor dispensing limits, if any, and circumstances under which such limits do not apply, under §105(a)(3);

(G) the amount of per-prescription enrollee charges, if any, under §201(b), including:
   (i) co-payments, co-insurance, deductibles or other charges;
   (ii) the amount of a per-person or per-family cumulative limit for such charges;
   (iii) classes of pharmaceuticals that are exempt from such charges; and
   (iv) enrollee rights to covered pharmaceuticals if such charges are not paid;

(H) enrollee rights to privacy of information relating to pharmaceuticals and pharmaceutical services provided under this Agreement, which shall include:
   (i) any persons or entities to which such information may be disclosed; and
   (ii) reasons for which disclosure may occur;\textsuperscript{31} and

(I) a general explanation of the types of information that must be made available under paragraph (2) and how an enrollee may gain access to or receive such information;

(2) make available to enrollees upon request the following types of information:\textsuperscript{32}

(A) information on Contractor’s use, if any, of a drug formulary under §105(b)(1), including:
   (i) an explanation of Contractor’s drug formulary including:

\textsuperscript{31} \textbf{Commentary}: For example, disclosure between network pharmacies may occur in order to identify potentially harmful interactions among medications prescribed for an enrollee by different providers and obtained at different pharmacies.

\textsuperscript{32} \textbf{Commentary}: Means of making the information available may include hard copy lists of, for example, formulary or prior authorization drugs at network pharmacies, through a telephone hotline or at an Internet site (that beneficiaries may be able to access at a public library or other site).
(I) the implications of the formulary for enrollee access to covered pharmaceuticals;

(II) differential enrollee charges, if any, for on- and off-formulary pharmaceuticals;

(III) the possibility that pharmaceuticals may in the future be added to or dropped from the formulary;

(IV) the availability of current information on which drugs are included in the formulary;

(if applicable, (V) the possibility that a formulary drug may be subject to prior authorization;)

and

(ii) the identity of covered pharmaceuticals or classes or uses of covered pharmaceuticals that are included in Contractor’s drug formulary;\(^{33}\)

(B) information on Contractor’s prior authorization procedures for covered pharmaceuticals\(^{34}\) under §105(b)(2), including:

(i) an explanation of Contractor’s prior authorization program including:

(I) implications of prior authorization for enrollee access to covered pharmaceuticals;

(II) Contractor duties to respond to an authorization request within 24 hours and to provide at least a 72-hour supply of a pharmaceutical for an emergency medical condition;

(III) the possibility that pharmaceuticals subject or exempt from prior authorization may change in future;

(IV) the availability of current information on which drugs are included in the formulary; and

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\(^{33}\) **Commentary:** Drafter may wish to require provision of the list of formulary pharmaceuticals that is current for the year in which it is to be provided, supplemented by notices of or telephone hotline information on any changes in the formulary since it was compiled for that year.

\(^{34}\) **Commentary:** This specification refers to prior authorization standards that apply specifically to pharmaceuticals under federal Medicaid law, §1927(d)(5) of the Social Security Act, 42 U.S.C. §1396-8(d)(5). See *infra, §105(b).* Drafter may wish to consider these standards in conjunction with coverage determination standards and procedures that are generally applicable to all covered benefits, including pharmaceuticals.
(if applicable, (V) the possibility that a formulary 

drug might be subject to prior authorization); and

(ii) the identity of covered pharmaceuticals or classes of 

pharmaceuticals that are subject to prior authorization;

(C) information, including implications for enrollee access to 

covered pharmaceuticals, of Contractor’s other coverage 
determination standards and procedures under §105, if any, that 

may affect coverage of pharmaceuticals;

(D) Contractor’s use of disease management program(s) (as 

defined in §106(a)(5)) (if any) that relate to pharmaceuticals and/or 

pharmaceutical services covered under this Agreement; such 

information shall include:

(i) condition(s) for which such programs are offered;

(ii) an explanation of procedures and goals of the program; and

(iii) how an enrollee may qualify for participation in such a program; and

(E) whether Contractor or Contractor’s clinical or pharmacy 

providers may qualify for financial or professional incentives or 

disincentives relating to usage of specific pharmaceuticals.³⁵

§105. Medical Necessity and Other Coverage Determination Standards and 

Procedures

(a) Medical Necessity — In making medical necessity decisions or prior 

authorization decisions relating to pharmaceuticals and pharmaceutical services, 

Contractor shall use the following standards:³⁶

³⁵ Commentary: This provision is not intended to require disclosure of the exact nature or amount of such 
incentives or disincentives. However, the use of any types of manufacturer incentives (e.g., discounted 
pricing, gifts, business courtesies including grants and “value-added” programs) in connection with 
promoting the use of a manufacturer’s drug may violate federal and state anti-kickback laws. Full 
disclosure of such incentives as are permitted under narrow “safe harbor” exceptions to federal Medicare 
anti-kickback law (applicable also to Medicaid-financed drugs) is recommended by legal experts. See TN 
Bulleet, JH Krause. “Kickbacks, Courtesies or Cost-effectiveness: Application of the Medicare 
Antikickback Law to the Marketing and Promotional Practices of Drug and Medical Device 

³⁶ Commentary: Under standards that apply to Medicaid benefits generally, federal regulations allow a 
Medicaid agency to limit coverage to that which is “medically necessary or through utilization review.” 42 
C.F.R. §440.230(d). Coverage of a benefit must be sufficient in amount, scope and duration to reasonably 
achieve the “purpose” of the benefit, and coverage limits may not be imposed in a way that discriminates
(1) the standard of coverage to be used for coverage determinations is as follows.\textsuperscript{37}

(A) the amount, duration and scope of coverage for each covered pharmaceutical shall be sufficient in amount, duration and scope to reasonably achieve its purpose;\textsuperscript{38}

(B) any limits on coverage imposed by Contractor on any covered pharmaceutical shall not arbitrarily deny or reduce coverage on the basis of an enrollee's diagnosis or type of illness or condition;

(and, to the extent that Purchaser elects to make state Medicaid law directly applicable to Contractor:\textsuperscript{39} (C) the amount, duration and scope of coverage for each covered pharmaceutical shall not be less than that to which an enrollee is entitled under [drafter insert reference to State Medicaid Plan]);

(2) the following types of evidence shall be taken into account.\textsuperscript{40}
(A) clinical evidence (including evidence of drug resistance) of the health status and needs of the enrollee for whom the coverage decision is being made;

(B) the recommendation of the provider who prescribed the pharmaceutical;

(C) the opinions of medical and other health care providers who are experienced in the age-appropriate treatment and medication of individuals with physical or mental illnesses or conditions similar to or the same as that of the enrollee for whom the coverage decision is being made;

(D) the opinions of Contractor's pharmacy and therapeutics committee under subsection (b)(1)(A) and Contractor's drug use review board under §204(a)(1); and

(E) professional standards of medical, pharmacy, public health, mental health and other health care practice as reflected in:

   (i) standards of care of public health agencies with the responsibility of disease prevention and control in Contractor’s service area;\footnote{Commentary: In accordance with their legal duty to control and prevent such diseases and conditions as tuberculosis, sexually transmitted diseases, and childhood lead poisoning, public health agencies may use clinical guidelines published by the Centers for Disease Control and Prevention and/or other clinical guidelines that are appropriate for populations in their service areas, many of whom may be Medicaid beneficiaries. Such agency guidelines may include recommendations of the Centers for Disease Control and Prevention, the Federal Advisory Committee on Immunization Practices or the New York State AIDS Institute.}

   (ii) clinical guidelines and professional consensus statements developed with the support of government agencies or nonprofit organizations;\footnote{Commentary: Consensus guidelines, reflecting reviews and analyses of peer-reviewed literature and consultation among experts, are developed by the National Institutes of Health, among others.}

   (iii) scientific literature published in peer-reviewed journals;

(3) In the case that Contractor limits the total number of prescriptions (including refills) that are covered for an enrollee within a specified period of time, it shall be medically necessary to cover all covered
pharmaceuticals, including those exceeding such limit, prescribed for an enrollee diagnosed with one or more co-existing conditions for which:

(A) multiple drug therapies are prescribed to treat an individual condition; or

(B) drug therapies are prescribed for treatment of multiple co-existing conditions;

(4) Contractor shall not deny, terminate or restrict coverage in whole or in part any covered pharmaceutical for an individual enrollee solely for one or more of the following reasons:

(A) one or more of an enrollee’s characteristics or social circumstances may complicate a course of pharmaceutical therapy prescribed for the enrollee;

(B) the enrollee for whom the covered pharmaceutical is prescribed is a minor, if the minor is permitted under [drafter insert applicable state law relating to minor rights to consent to medical treatment and any parental notification requirement] to

43 Commentary: This provision is drafted to ensure that the treatment of enrollees requiring multiple pharmaceutical therapies is not compromised by medically inappropriate coverage restrictions for pharmaceuticals that a beneficiary cannot otherwise afford. Medicaid law specifically allows a state agency to limit the total number of prescriptions (including refills) for drugs in a therapeutic class. §1927(d)(6) of the Social Security Act, 42 U.S.C. §1396r-8(d)(6). A state agency (or MCO) may also require an enrollee undergo one or more unsuccessful trials (“treatment failures”) with a pharmaceutical other than that prescribed by the treating provider, as a condition of coverage for the drug as prescribed. The agency may impose such requirements on certain drugs under its duty to employ program payment methods that are “consistent with efficiency, economy, and quality of care.” §1902(a)(30)(A) of the Social Security Act, 42 U.S.C. §1396a(a)(30)(A). The appropriateness of a “treatment failure” requirement varies with diagnoses and with the medical history and status of individual patients. For example, a short trial with over-the-counter nonsteroidal anti-inflammatory drugs may be appropriate for mild osteoarthritis, but a treatment failure with tuberculosis or other infectious diseases could promote the development of drug-resistant infectious organisms, complicating treatment of an individual and creating substantial public health risks. Drafter may wish to prohibit treatment failure requirements for certain classes of drugs or drug uses.

44 Commentary: An individual’s ability to adhere to pharmaceutical therapy may be affected by the complexity and duration of a drug treatment regime, by adverse side-effects of prescribed drugs, by drug costs, by barriers to appropriate care, by unstable living circumstances (e.g., homelessness) or other factors. However, researchers have been unable to identify a factor or combination of factors that permit accurate prediction of an individual’s capacity to follow a drug treatment regimen successfully. See R.D. Moore, et al., “Cost-effectiveness of Directly Observed versus Self-Administered Therapy for Tuberculosis,” Am J. Respir Crit Care Med 1996; 154:1013-1019. Purchaser and Contractor may wish to work with public health agencies, shelters for the homeless and other organizations that provide supportive services, including directly observed therapy, for individuals who may experience drug therapy adherence problems.

45 Commentary: At the time these specifications were drafted, 25 states and the District of Columbia by law specifically permitted minors to consent to contraceptive services. All states by law permitted minors to consent to diagnosis and treatment of a sexually transmitted disease. Parental notification may or may not be required. Karen Hein, “Annotation: Adolescent HIV Testing – Who Says Who Signs?” AJHP
consent to the prescribed pharmaceutical therapy;

(C) the pharmaceutical is approved under accelerated approval procedures required under 21 C.F.R. §§312.80 et seq. and 314.500 et seq.;46

(D) the pharmaceutical is available free of charge or at a discount through a publicly assisted provider (whether or not the provider participates in Contractor’s provider network); or

(E) the pharmaceutical is one that was supplied under §201(a) to certain providers, from whom an enrollee obtained the pharmaceutical; and

(5) Contractor shall exempt from medical necessity decisions or prior authorization decision a pharmaceutical that is:

(A) prescribed, administered or supplied to an enrollee for an emergency medical condition (as defined in §106(a)(8));47 or

(B) ordered for an enrollee by a court of competent jurisdiction.48

(b) Procedures for Use of Formularies and Prior Authorization of Pharmaceuticals — In using a formulary or prior authorization relating to coverage of pharmaceuticals, Contractor shall use the following procedures.49

46 See supra, Commentary 10, for discussion of accelerated drug approval procedures for drugs for serious, life-threatening conditions.
47 Commentary: The Balanced Budget Act of 1997 prohibits prior authorization by a MCO of items or services provided to treat an emergency condition for a Medicaid beneficiary, regardless of whether such items or services were furnished by a provider under contract to the MCO. §1932(b)(2)(A) of the Social security Act, 42 U.S.C. §1396u-2(b)(2)(A). The definition of “emergency condition” used in the Act is shown in §106(a)(8). In addition, Federal Medicaid law relating specifically to coverage of outpatient prescription drugs requires a 72-hour supply of a drug to be dispensed pending a prior authorization decision for its coverage by a Medicaid agency; this specific requirements is shown in subsection (b)(2)(B). This specification is drafted to apply both to coverage decisions, as distinguished from quality-related drug use review activities described at §204(a). The specification should not be interpreted to preclude prospective or retrospective drug use review, as described in §204(a)(3) and (4) for purposes of quality measurement and improvement.
48 Commentary: For example, a court may order a parent with addiction disorder to undergo treatment for this condition in order to regain custody of a child removed from the family home because of abuse or neglect. Such treatment may include pharmaceutical therapy.
49 Commentary: The specifications in this subsection address standards for coverage decisions of general applicability, i.e., those that apply to enrollees generally as opposed to decisions about coverage for individual enrollees.
(1) Contractor may use a drug formulary only if the formulary is administered in accordance with the procedures in subparagraphs (A) and (B).\textsuperscript{50} 

(A) Contractor shall establish a pharmacy and therapeutics committee which shall:

(i) include network physicians and pharmacists who have recognized knowledge and expertise in the areas described in §204(a)(1)\textsuperscript{51} for Contractor’s drug use review (DUR) program and who practice in the Service Area to which the Agreement applies; and

(ii) be responsible for the development and review of any drug formulary used by Contractor in carrying out this Agreement; and

(B) all pharmaceuticals covered under §103(a) shall be included in the formulary; a covered pharmaceutical for treatment of a specific condition in an identified population (if any) shall not be excluded from the formulary unless:

(i) the pharmacy and therapeutics committee determines that it does not have a clinically therapeutic advantage in terms of safety, effectiveness, or clinical outcome, with respect to a specific disease or condition or population (if any), over other drugs included in the formulary; and

(ii) the determination is based on the pharmacy and therapeutics committee’s review of the drug’s labeling

\textsuperscript{50}\textbf{Commentary}: This subsection is based on formulary standards in federal Medicaid law, §1927(d)(4) of the Social Security Act, 42 U.S.C. §1396r-8(d)(4). A drug formulary is a list of covered drugs that is used by third party payers, hospitals and other entities to control pharmaceutical costs. In private sector usage, inclusion of a pharmaceutical in a formulary may be required for coverage, or formulary status affect the enrollee’s level of copayments for drugs, see S.O. Schweitzer, \textit{Pharmaceutical Economics and Policy} (Oxford University Press (1997)). Federal Medicaid standards for drug formularies differ from this usage in two respects that are reflected in this specification. First, formulary as well as off-formulary drugs may be subject to prior authorization. Second, except for ten classes of drugs, identified in federal Medicaid law and set out \textit{supra} at \textbf{Commentary 27}, a covered drug (i.e., under rebate agreement, approved under FDCA and prescribed for approved use or use reported in compendia) must be available through prior authorization, meeting specialized standards set at §105(c). 

\textsuperscript{51}\textbf{Commentary}: These specifications assume that two distinct network committees will be responsible for Contractor’s formulary as described in this subsection and for Contractor’s drug use review program as described at §204(a). Federal Medicaid law provides for two such separate entities, but also suggests that the functions be combined in a single committee. §1927(d)(4)(A) of the Social Security Act, 42 U.S.C. §1396r-8(d)(4)(A). Integration of the two functions into a single committee would permit formulary choices to be informed by drug use data developed in DUR activities.
under the FDCA or, in the case of an off-label use, review of the compendia identified in §103(a)(1)(B)(ii);\(^{52}\)

(iii) Contractor provides a written explanation, available to the public, of why the pharmaceutical is excluded from the formulary; \(^{53}\)

(iv) except for pharmaceuticals identified in §103(c), Contractor makes each pharmaceutical excluded from the formulary available through a prior authorization procedure authorization as described at paragraph (2) of this subsection; \(^{54}\)

\[(and \ (C) \ if \ Purchaser \ elects \ to \ make \ Federal \ Medicaid \ law \ directly \ applicable \ to \ Contractor, \ Contractor \ complies \ with \ such \ other \ requirements \ as \ the \ Secretary \ of \ Health \ and \ Human \ Services \ may \ make \ applicable \ to \ Medicaid \ in \ order \ to \ achieve \ program \ savings \ consistent \ with \ protecting \ the \ health \ of \ Medicaid \ beneficiaries);\]

(2) Contractor may require prior authorization of a covered pharmaceutical provided that the prior authorization procedures: \(^{55}\)

(A) require a response to an authorization request, by telephone or other telecommunication device, within 24 hours of the request;

(B) permit dispensing of at least a 72-hour supply of the pharmaceutical for an emergency medical condition (as defined in §106(a)(8)); and

(C) in the case that authorization is denied, provides for a written explanation of the reason for denial.

\(^{52}\) **Commentary:** Drafter may wish to specify additional types of information that should be taken into consideration in formulary decisions including, as appropriate, certain types of evidence identified in subsection (a)(2) for coverage decisions relating to individual enrollees. Such evidence might include: (1) professional standards as defined in subsection (a)(2)(E) and (2) opinions and recommendations of practitioners with specialized experience and expertise in providing pharmaceutical therapies to Medicaid populations including those in the communities served by Contractor. Contractor could also (3) establish an enrollee advisory panel and/or (4) consider data and experience obtained from Purchaser’s and Contractor’s operations. These types of information could contribute to more informed formulary choices that would, for example, relate to acceptability of pharmaceutical therapies within the community served by Contractor, or that would take into account pharmaceutical actions that may differ from populations that participate in controlled clinical drug trials.

\(^{53}\) **Commentary:** The availability of a written explanation of a formulary exclusion is specifically required under federal Medicaid law for Medicaid fee-for-service drug formularies. §1927(d)(4)(C), 42 U.S.C. §1396r-8(d)(4)(C).

\(^{54}\) **Commentary:** An alternative option would be to require Contractor to cover a pharmaceutical excluded from its formulary if the provider certified its medical necessity and the pharmaceutical is covered under Purchaser’s State Medicaid Plan.

\(^{55}\) §1927(d)(5) of the Social Security Act, 42 U.S.C. §1396r-8(d)(5).
(c) **Continuity of Pharmaceutical Therapy** — In the case that Contractor modifies the formulary status of a covered pharmaceutical or requires prior authorization or an enrollee co-payment as a condition of coverage, after an enrollee has begun a course of therapy with the pharmaceutical, Contractor shall:

(1) provide an individual notice and explanation of the modification to each enrollee:

   (A) at the next time that the enrollee requests a prescription refill of the pharmaceutical; or

   (B) at least [drafter specify time period] before the effective date of the exclusion; 56 and

(2) continue to cover and provide or arrange for the provision of the pharmaceutical under the same terms and conditions as before the modification until the earliest of:

   (A) completion of the pharmaceutical therapy (including any needed refills);

   (B) the first refill request after the enrollee has received the notice and explanation;

   (C) enrollee’s next scheduled visit with the prescribing provider; or

   (D) [drafter specify time period]. 57

§106. Definitions

(a) **General Rule** — Terms in this Agreement shall have the following meanings:

(1) **Agreement** – the legally binding contract under which Contractor obligates itself to a Purchaser to provide pharmaceutical benefits and services as described in this Agreement.

56 **Commentary**: Printed notices of formulary changes could be provided to enrollees with prescription refills for pharmaceuticals affected by such changes. Drafter may wish to specify minimum information standards for such notices, including the effective date of the exclusion, an explanation of the effect of the exclusion (e.g., availability of alternative medication on formulary), an explanation of temporary continuation of coverage as described under paragraph (1) of this subsection, and a recommendation that the enrollee contact prescribing provider to discuss continuing pharmaceutical therapy.

57 **Commentary**: Time periods could be selected to allow enough time to allow: (a) an enrollee and prescribing provider consultation about alternative pharmaceuticals in Contractor’s formulary; (b) a final decision in an enrollee or provider appeal for continuing coverage of the pharmaceutical; and (c) an enrollee determination of whether another Medicaid managed care plan offers the excluded pharmaceutical on more favorable terms to disenroll from Contractor’s plan and enroll in an alternative plan.
(2) **Contractor**—the party to this Agreement that agrees to provide pharmaceutical benefits and services in accordance with the terms and conditions of the Agreement.

(3) **Coverage Decision**—any decision made by Contractor relating to the eligibility of an enrollee for a pharmaceutical benefit or service covered under the Agreement when the decision results in the approval, denial, termination, or restriction of coverage of a covered pharmaceutical or service or the substitution of a “generic” or “therapeutically equivalent” drug for that prescribed by enrollee’s clinical provider. Such decisions include determinations of “medical necessity” and decisions resulting from prior, concurrent or retrospective authorization procedures.

(4) **Covered Pharmaceuticals and Pharmaceutical Services**—the pharmaceuticals and pharmaceutical services set out in §103(a) and (b) that Contractor is required to furnish to an enrollee consistent with the coverage determination standards and procedures set forth in §105.

(5) **Disease Management Program**—a diagnosis-specific health care

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**Commentary:**

- The “Contractor” is the organization that contracts to furnish pharmaceutical benefits and services set out in an executed (legally binding) Agreement to provide pharmacy coverage for Medicaid managed care enrollees. Note that under §101(a), the terms and conditions of the Agreement apply to any other person or entity to which Contractor delegates any of its duties under the Agreement. The applicability of individual terms and conditions to a subcontractor, person or entity would depend on terms and conditions included in a subcontract and subcontractor agreements with individual providers. For example, a pharmacy subcontractor may purchase prior authorization and utilization review services from a vendor of such services. Both the Contractor and the subcontractor would remain legally responsible for ensuring that these functions are carried out as specified in the Agreement(s).

- An additional option would be to specify that failure of the Contractor to make a final decision within a specified period of time would be considered a “coverage decision.”

- Because there is no one generally-accepted definition of “disease management,” this definition includes the range of activities that may singly or in combination constitute this function. For purposes of this Agreement, such activities and combinations should be considered “disease management” even if another name is used for them. The definition is based on descriptions of disease management programs in Karen Brodsky, *Pharmacy Benefit Management Directory and Resource Guide* (Aspen Publishers, Inc. (1997)); SO Schweitzer, *Pharmaceutical Economics and Policy* (Oxford University Press (1997)); and Disease Management Association of America (DMAA), *The Disease Management Association of America Releases the First Comprehensive Definition of Disease Management* (Press Release (October 20, 1999)). The definition adopted by the DMAA Board is:

  “Disease management is a multi disciplinary, continuum-based approach to health care delivery that proactively identifies populations with, or at risk for, established medical conditions that:

  - supports the physician/patient relationship and plan of care;
  - emphasizes prevention of exacerbations and complications utilizing cost-effective evidence-based practice guidelines and patient empowerment strategies such as self-management education; and
  - continuously evaluates clinical, humanistic, and economic outcomes with the goal of improving overall health.

  In addition, DMAA recommends that all of the following components be in place in order for a program to be considered a disease management program:

  - Population identification process;
program that is intended to improve patient outcomes and that includes one or more of the following components:

(A) specific clinical objectives or outcomes to be achieved;

(B) a process for identifying enrollees with the condition that the program addresses;

(C) patient education and support, which may address diet, exercise and other “lifestyle” factors, self-monitoring and or appropriate medication use and may include patient reminders to refill prescriptions;

(D) evidence-based or other types of practice guidelines or protocols (if any) for management of the target condition;

(E) monitoring patient and/or provider adherence to guidelines or protocols;

(F) routine reporting or “feedback” to the enrollee, provider, health plan and ancillary providers;

(G) practice profiling of health care providers and ancillary providers;

(H) patient and or provider incentives for adherence to the protocols;

(I) measurement of the extent to which established outcomes are achieved and procedures are followed;

(J) integrated medical and pharmacy information systems;

(K) coordination of prescribing and dispensing practices;

(L) development of tools for primary care providers; and

- Evidence-based practice guidelines;
- Collaborative practice model to include physician and support-service providers;
- Risk identification and matching of interventions with need;
- Patient self-management education (may include primary prevention, behavior modification programs, and compliance/surveillance);
- Process and outcomes measurement, evaluation, and management;
- Routine reporting/feedback loop (may include communication with patient, physician, health plan and ancillary providers, and practice profiling);
- Appropriate use of information technology (may include specialized software, data registries, automated decision support tools, and call-back systems.”
(M) coordination of multiple treatment protocols for an individual patient.

(6) **Drafter** – state Medicaid agency counsel or other person or organization that is drafting and/or revising the Agreement.

(7) **Drug**\(^6\) – a simple or compound substance or mixture of substances that is prescribed for the cure, mitigation or prevention of disease or for maintenance of health that is prescribed and dispensed by appropriately licensed health care professionals.

(8) **Emergency Medical Condition**\(^6\) – a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such 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:

(A) the placing of the health of [an] individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy;

(B) serious impairment to bodily functions; or

(C) serious dysfunction of any bodily organ or part.

(9) **Generic Drug** – a drug as defined in [drafter insert reference to state law].\(^6\)

(10) **Purchaser** – the party to this Agreement that agrees to purchase

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\(^6\) **Commentary**: This specification sets out the definition of a “prescribed outpatient drug” in federal Medicaid regulations, 42 C.F.R. §440.120(a).


\(^6\) **Commentary**: Pharmacist dispensing of a “generic” or “generically equivalent” drug instead of a prescribed brand-name drug is regulated under state law. The inclusion of a definition of generic drugs would apply, under these specifications, only for purposes of drug utilization review under §204(a) and data collection and reporting requirements at §205(b) and (c). Federal Medicaid law does not address uses of generic and “therapeutically equivalent” drugs except to define “therapeutic equivalence,” pharmaceutical equivalence” and “bioequivalence” for purposes of pricing agreements between CMS and pharmaceutical manufacturers. §1927(k)(7) of the Social Security Act, 42 U.S.C. §1396r-8(k)(7). Virtually all states either require or allow a pharmacist to make such generic substitutions unless the prescribing provider indicates on the prescription that only the brand name version is to be dispensed. Prior notice to or approval of the prescribing provider is not required. State laws typically define a generic or generically equivalent drug as one that, compared with the brand name version, has the same active ingredient(s), strength or concentration, dosage form, and route of administration and that also is formulated to meet the same compendia and other standards (i.e., strength, quality, purity, and identity), but that may differ from the brand version in such characteristics as shape, scoring, configuration, packaging, excipients (including colors, flavors, and preservatives) and expiration time.
covered pharmaceuticals and pharmaceutical services for Medicaid managed care enrollees.

(and, if applicable: (11) Therapeutically Equivalent Drug – a drug as defined in [drafter insert reference to state law]).

65 Commentary: Pharmacist dispensing of a “therapeutically equivalent” drug instead of the drug prescribed by the treating clinician is regulated under state law. The inclusion of a definition of a therapeutically equivalent drug would apply, under these specifications, only for purposes of drug utilization review under §204(a) and data collection and reporting requirements at §205(b) and (c). In general, a pharmacist may not dispense a pharmaceutical with a different active ingredient (i.e., different chemical structure) but the same therapeutic effect (e.g., relief of symptoms) as that prescribed for an individual. Such a “therapeutic substitution” must be approved in advance by the prescribing provider and the approved substitution would be considered a new prescription. Pharmacists may have limited prescribing authority under collaborative agreement or other arrangements under state law. See supra, Commentary 24 for discussion of collaborative agreements.
Part 2. Service Delivery and Health Care Quality Measurement and Improvement

§201. Enrollee Access to Pharmaceuticals
§202. Enrollment and Disenrollment
§203. Provider Network
§204. Quality Measurement and Improvement
§205. Data Collection and Reporting
§206. Information for Providers
§207. Submission of Materials to Purchaser

§201. Enrollee Access to Pharmaceuticals

(a) Supply of Covered Pharmaceuticals for STDs to Clinical Providers

Upon request, Contractor shall supply the pharmaceuticals described in paragraph (1) in accordance with paragraph (2) to [drafter identify classes of participating clinical providers].

(1) The pharmaceuticals described in this paragraph are pharmaceuticals for prevention or treatment of sexually transmitted disease and for contraceptive purposes.

(2) The pharmaceuticals described in paragraph (1) shall be supplied in quantities that are sufficient to be:

(A) administered or provided in a “starter” dose to an enrollee during the enrollee's visit for health care services;

(B) administered, provided or prescribed for an enrollee for purposes of emergency contraception;

Commentary: This provision is not intended to create obligations in managed care clinical providers to maintain inventories of specified classes of pharmaceuticals; instead, it obligates the Contractor to supply pharmaceuticals to clinical sites as specified by the Purchaser and agreed to by Contractor. The provision reflects the public health priority of reducing “missed opportunities,” while a patient is at a clinical service site, to initiate drug therapies and promote preventive measures in order to interrupt transmission of sexually transmitted diseases (STDs) and HIV and to prevent unintended pregnancies. Sites serving enrollees at risk for STD, HIV and unintended pregnancy include those furnishing perinatal, family planning and adolescent outpatient services, STD and HIV service sites, and sites for individuals with behavioral health disorders (i.e., addiction disorder, mental illness). Drafter may wish to review state law relating to the authority of licensed health care providers to dispense as well as prescribe pharmaceuticals. Note that federal Medicaid law requires that enrollees in mandatory managed care programs operating under Section 1915(b) waivers be permitted to refer themselves to family planning providers, who may provide STD services as well as contraceptive services. §1915(b)(4) of the Social Security Act, 42 U.S.C. §1396n(b)(4). For purposes of Contractor’s development of a capitation fee inclusive of such pharmaceuticals, Purchaser may wish to clarify the scope of enrollee's rights to “self-refer” for pharmaceuticals supplied under this subsection.


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(C) in the case of condoms, to be provided in a reasonable number at enrollee request at the time of an enrollee’s visit for health care services.

(b) **Enrollee Cost-sharing** — Contractor may require enrollee cost-sharing for covered pharmaceuticals, not to exceed [drafter insert rate(s) of enrollee co-payments for prescription or other co-insurance or deductibles that may be applicable to each pharmaceutical prescription or refill; also insert cumulative total, if any, of such co-payments that may be charged to an enrollee or an enrolled family] and only if:

(1) no enrollee co-payment or cost-sharing charge is imposed on a pharmaceutical or pharmaceutical service that is provided for or to an enrollee:

(A) who is under [drafter specify age at which EPSDT eligibility ends in state Medicaid plan];

(B) who is pregnant [drafter specify pregnancy-related coverage in

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**Commentary:** HCFA considers Mifepristone (Mifeprex or RU-487), a drug approved by the FDA for terminating a pregnancy, to be subject to federal restrictions on Medicaid funding for abortions. Such funding is available only for procedures that voluntarily terminate a pregnancy resulting from rape or incest or in the case of a life-threatening physical disorder of the patient. State funds may be used to finance termination of pregnancies for other reasons in accordance with state law. March 30, 2001 letter of Penny R. Thompson, Acting Director of HCFA Center for Medicaid and State Operations, to State Medicaid directors, www.hcfa.gov/medicaid/smd33001.htm. Purchaser and Contractor may wish to clarify record-keeping or other arrangements to ensure appropriate allocation of state and federal funds under the Agreement for pharmaceuticals used to terminate a pregnancy.

**Commentary:** Federal Medicaid law allows “nominal” enrollee co-payments or other charges for covered services (including pharmaceuticals), with certain exceptions, and prohibits providers from withholding covered services from a Medicaid beneficiary because of non-payment of such charges. Federal Medicaid regulations define a “nominal” co-payment as: “a standard or fixed co-payment” for a covered service, which is calculated by applying the maximum co-payment amounts specified in regulation to a Medicaid agency’s “average or typical payment” for the service. Maximum amounts are: $.50 for a service for which the agency pays $10 or less; $1.00 for a $10.01 to $25.00 service; $2.00 for a $25.01 to $50.00 service; and $3.00 for a service for which the agency pays $50.01 or more.” The example provided in the regulation is a co-payment of $.50 if “the agency’s typical payment for prescribed drugs is $4 to $5 per prescription.” The regulation also permits an agency to provide for a maximum, cumulative amount of co-payment or other cost-sharing charges imposed on a Medicaid family within a specified time period. No example of a cumulative limit is given. §1903(o), 1916 of the Social Security Act, 42 U.S.C. §1396b(o), 1396o, 42 C.F.R. §§447.54, 55. (In addition to the exemptions shown in this subsection, Medicaid law prohibits copayments for services in inpatient, nursing facility, intermediate care and other medical facilities and hospice care; because drugs provided in these settings would be included in reimbursements to the facilities, the exemptions are not addressed in this document.)

**Commentary:** At a minimum, Medicaid beneficiaries under age 18 must be exempt from any cost-sharing or charges for Medicaid services but a state may also exempt individuals under 21, 20 or 19 years of age “or any reasonable category of individuals 18 years of age or over.” §1916(a)(2)(A) of the Social Security Act, 42 U.S.C. §1396o(a)(2)(A).
state Medicaid plan];\(^71\)

(C) for an emergency condition (as defined in §106(a)(8));\(^72\) and

(D) for family planning services and supplies;\(^73\) and

(2) no covered pharmaceutical prescribed for an enrollee is withheld because of enrollee’s inability to pay such co-payments or other charges.

§202. Enrollment and Disenrollment\(^74\)

(a) Safeguards Against the Interruption of Pharmaceutical Therapy at Time of Enrollment — In the case of an individual who, at the time of enrollment with Contractor, is receiving prescribed pharmaceutical therapy, Contractor shall cover and furnish or arrange for such therapy until the primary care provider selected by the enrollee (or to whom the enrollee is assigned) has:

(1) assessed the enrollee’s condition;

(2) reviewed the enrollee’s care; and

(3) prescribed or arranged for uninterrupted pharmaceutical therapy that is appropriately determined in accordance with coverage determination standards and procedures at §105.

(b) Safeguards Against the Interruption of Pharmaceutical Therapy at Time of Disenrollment — In the case of an individual who ceases to be an enrollee with Contractor and who, at the time of disenrollment, is receiving prescribed pharmaceutical therapy, Contractor shall:

(1) continue to cover and provide or arrange for such therapy until the

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\(^{71}\) **Commentary:** At a minimum services related to pregnancy and any complicating condition (and, at a state's option, any other condition in a pregnant woman) must be exempt from copayments. §1916(a)(2)(B) of the Social Security Act, 42 U.S.C. §1396o(a)(2)(B).


\(^{73}\) Id.

\(^{74}\) **Commentary:** This Section was drafted, as recommended by experts in public health and chronic conditions, to prevent or minimize drug therapy interruptions or discontinuation that could result in treatment failure for serious or life-threatening conditions, promotion of drug-resistant infectious agents or other adverse outcomes. See also §105(e) which addresses continuation of drug therapy at time of changes in formularies or other coverage limitations. Federal Medicaid law does not address this issue directly; however, certain state Medicaid contracts provide for continuation of covered services or, specifically, continuation of drug therapy prescribed before a beneficiary enrollee enrolls in managed care, for a specified period of time or until the new enrollee is evaluated by his or her primary care contractor. See Sara Rosenbaum, et al., *Negotiating the New Health System: A Nationwide Study of Medicaid Managed Care Contracts*, 3rd Ed. (1999), GWU Center for Health Services Research and Policy, Vol. 2, Pt. 1, Table 1.4, www.gwhealthpolicy.org.
earliest of:

(A) completion of the pharmaceutical therapy;

(B) the day on which another provider or managed care organization assumes responsibility for the care of the individual; or

(C) the last day of the period for which a premium has been paid for coverage under this Agreement for the former enrollee;

and

(2) in the case that the individual does not have other third-party coverage at time of disenrollment, offer and provide assistance to the enrollee in identifying alternative sources of payment for the pharmaceutical therapy, [drafter insert the names of the State Children’s Health Insurance Program, the state AIDS Drug Assistance Program under the Ryan White CARE Act, and any other drug assistance or health services program for low-income and/or uninsured individuals].

§203. Provider Network

(a) General Rule — Contractor shall maintain a staff or network of pharmaceutical providers that is sufficient to ensure adequate enrollee access to covered pharmaceuticals and pharmaceutical services and that shall include:

(1) network pharmacies that are so located within Contractor’s service area that no enrollee must travel more than [drafter insert distance or time

75 Commentary: For example, if the Contractor is paid on the first of the month on a per member, per month basis and an enrollee disenrolled on the 10th day of the month, the Contractor’s coverage obligation would continue through the last day of the month.

76 Commentary: Children and adolescents disenrolled because of loss of Medicaid eligibility may be eligible for alternative pediatric insurance through the State Children’s Health Insurance Program, Title XXI of the Social Security Act, 42 USC §1397 et seq.

77 Commentary: Modification of this provision may be required in a state with an “any willing provider” law that is applicable to pharmacists.

78 Commentary: If permitted under state law, an additional option would be to permit or require a Contractor to include in its network a pharmaceutical mail service, provided that the service is capable of delivering a prescribed covered pharmaceutical within 72 hours of the time that the enrollee presents a prescription to it and that an enrollee is not required to use such a service as a condition of pharmaceutical coverage. This option would respond to enrollee preferences for convenience (especially if the enrollee lives in an underserved rural or urban area or is being treated for a disabling condition) and confidentiality. However, the lack of discretionary income and the instability of housing for many low-income persons would make requiring use of a mail order service, or making use of a local pharmacy more costly, would be inappropriate for Medicaid managed care enrollees.

79 Commentary: “Staff” refers to health care professionals employed in a closed-panel health maintenance organization (HMO).
standard] to obtain covered pharmaceuticals and pharmaceutical services, and

(2) network pharmacies, network hospitals or other network providers that dispense pharmaceuticals on a 24-hour, 7-days a week basis that are so located within Contractor’s service area that no enrollee must travel more than [drafter insert distance or time standard appropriate for emergency access to pharmaceuticals] to obtain covered pharmaceuticals and pharmaceutical services.

(b) Capacity of Network Providers — Contractor shall ensure that network providers:

(1) in accordance with [drafter insert applicable state law], maintain an inventory of covered pharmaceuticals or access to such an inventory that is sufficient to fill and refill enrollee prescriptions at the time they are presented; and

(2) maintain a staff of pharmacists that is sufficient to offer pharmaceutical counseling to enrollees at the time that prescriptions are presented, under §103(b)(1).

§204. Quality Measurement and Improvement

(a) Drug Use Review — Contractor shall provide a drug use review (DUR) program that shall ensure that prescriptions for covered pharmaceuticals are appropriate, medically necessary, and unlikely to result in adverse medical results. The DUR program shall include:

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81 Commentary: To the extent permitted by state law, Contractor may meet this standard in rural and urban areas without sufficient free-standing pharmacies by arranging for prescribed drugs and biologicals to be dispensed after regular business hours and on weekends by other appropriately licensed entities (e.g., institutional pharmacies in rural health clinics or hospitals or individuals.)

82 Commentary: This subsection sets out components of the drug use review (DUR) programs that state Medicaid fee-for-service programs must maintain as a condition of receiving federal matching funds for their outpatient Medicaid drug costs. §1927(g) of the Social Security Act, 42 U.S.C. §1396r-8(g). As under Federal law, the focus of the specifications in this section is primarily quality assurance, as opposed to limitations on coverage addressed in §105. At the time these specifications were drafted, drug use review was not required under federal law for Medicaid managed care organizations but certain Medicaid managed care contracts addressed this issue. Contract specifications varied from requiring contractors to comply with the state agency’s drug use review program to using the agency’s standards or otherwise coordinating activities. See Repasch and Wehr, supra.

83 See also §205(c)(3) relating to collection and reporting of drug use review program data.
(1) a DUR program board which shall be responsible for activities described in this subsection and which shall include network physicians and pharmacists\textsuperscript{84} who have recognized knowledge and expertise in one or more of the following:

(A) the clinically appropriate prescribing of covered drugs and biological products;

(B) the clinically appropriate dispensing and monitoring of covered pharmaceuticals;

(C) drug use review, evaluation and intervention; and

(D) medical quality assurance;

(2) predetermined DUR program standards, which shall be:

(A) established by the DUR board described in paragraph (1);

(B) consistent with:

(i) the compendia enumerated in §103(a)(1)(B)(ii); and

(ii) peer-reviewed medical literature;

(C) reviewed and updated \textit{[drafter insert frequency of review and updating]} to ensure consistency with current knowledge described in the compendia and literature enumerated in subparagraph (B); and

(D) used to assess data on prescribed, covered pharmaceuticals on an ongoing basis to determine:

(i) therapeutic appropriateness;

(ii) over- and under-utilization;

(iii) appropriate use of generic products;

(iv) therapeutic duplication;

\textsuperscript{84} See discussion of integrating functions of the pharmacy and therapeutics committee (§105(b)(1)(A)) \textit{supra} at \textbf{Commentary 52}. Additional options would be to include clinicians with expertise in treatment of complex and co-morbid conditions (e.g., cancer, HIV and tuberculosis), clinicians practicing in the community served by the Contractor and/or enrollee representatives as designated by Purchaser. Federal Medicaid law does not address these types of expertise, which were recommended by drug experts and consumers reviewing the specifications.
(v) drug-disease contraindications;

(vi) drug-drug interactions;

(vii) interactions of drugs and herbal or other alternative remedies;\(^{85}\)

(viii) incorrect drug dosage or duration of drug treatment; and

(ix) clinical abuse and misuse;

(3) prospective review of prescriptions,\(^ {86}\) which shall:

(A) be provided at the point-of-sale or distribution at the time an enrollee prescription is filled or delivered;

(B) screen the prescribed pharmaceutical therapy, using the standards developed under paragraph (2), for potential problems relating to:

(i) therapeutic duplication;

(ii) drug-disease contraindications;

(iii) drug-drug interactions (including serious interactions with nonprescription or over-the-counter drugs);

(iv) interactions of drugs and herbal or other alternative remedies;\(^ {87}\)

(v) incorrect drug dosage or duration of drug treatment;

(vi) drug-allergy interactions; and

(vii) clinical use/abuse;

\(^{85}\) Commentary: Federal Medicaid law does not address including herbal and other alternative remedies in patients' pharmaceutical records; see Commentary 22 for discussion of potential adverse outcomes of drug-herbal remedy interactions.

\(^{86}\) Commentary: Drafter is advised to review state pharmacy practice law with regard to prospective review by pharmacists. In connection with prospective drug use review, federal Medicaid law encourages state Medicaid agencies to establish an electronic claims management “for the purpose of performing online, real-time eligibility verification, claims data capture, adjudication of claims, and assisting pharmacists (and other authorized persons) in applying for and receiving payment.” §1927(h) of the Social Security Act, 42 U.S.C. §1396r-8(h).

\(^{87}\) Commentary: Federal Medicaid law does not address including herbal and other alternative remedies in patients' pharmaceutical records; see Commentary 22 for discussion of potential adverse outcomes of drug-herbal remedy interactions.
(C) include enrollee counseling under §103(b)(1) using standards developed by the DUR board;

(D) include efforts by pharmacists participating in Contractor's provider network to obtain and record the following for each enrollee presenting a prescription to be filled:

   (i) name, address, telephone number and date of birth (or age);

   (ii) medical history where significant, including disease state or states, known allergies and drug reactions;

   (iii) a comprehensive list of medications (including herbal or other alternative remedies)\textsuperscript{88} and devices used by the enrollee; and

   (iv) any substitution of a different drugs than that prescribed by the enrollee’s treating provider; and

(E) be administered in a manner that prevents automatic denial or modification of a prescription before the dispensing pharmacist may exercise professional judgment with regard to the appropriateness for an enrollee of the prescribed pharmaceutical;\textsuperscript{89}

(4) retrospective review of prescriptions, which shall:

   (A) be administered by means of a mechanized claims processing and information retrieval system under §205(a) or otherwise; and

   (B) provide for ongoing, periodic examination of pharmaceutical claims data and other records in order to identify patterns among:

   (i) network providers who prescribe pharmaceuticals;

   (ii) network providers who dispense pharmaceuticals; and

   (iii) fraud, abuse, gross overuse, or other inappropriate or medically unnecessary care with regard to covered

\textsuperscript{88} Id.

\textsuperscript{89} Commentary: The issue of automatic modification of a prescription at time of dispensing is not addressed in Medicaid law. The policy in this specification was recommended by reviewers of these specifications, including drug experts and consumer representatives. This specification is drafted to be consistent with the deference in federal Medicaid law to the professional judgment of pharmacists. Drafter may wish to review state pharmacy practice law as it may apply to use of automatic prescription overrides in an electronic prospective review program.
pharmaceuticals; and

(5) an educational program consisting of ongoing provider education and outreach programs that provide:

(A) education of providers participating in Contractor's provider network on common drug therapy problems for the purpose of improving prescribing and dispensing practices; and

(B) ongoing interventions (in drug therapies, prescribing practices, and dispensing practices as identified in the retrospective claims review described in paragraph (4)) with providers participating in Contractor's provider network who prescribe and dispense pharmaceuticals, including:

(i) dissemination of information about the retrospective review program;

(ii) written and face-to-face interventions with network providers; and

(iii) intensified review or monitoring of selected providers participating in Contractor's provider network who prescribe and dispense pharmaceuticals; and

(6) an annual report on DUR program activities under §205(c)(2).

(b) Use of HEDIS Quality Measures — Contractor shall collect and use, in its quality measurement and improvement program, data for such current HEDIS measures adapted for Medicaid managed care as may relate to pharmaceutical benefits and services.

(c) Disease Management Outcomes — In the case that Contractor provides one or more disease management programs (as defined in §106(a)(5)), Contractor shall, with Purchaser, establish appropriate outcomes for such program and measure the extent to which the program(s) achieve the outcomes.

90 Commentary: Consistent with federal Medicaid law, Contractor may elect to meet this standard by contracting with an accredited health care educational institution, a state medical society, a state pharmacist association or other appropriate organization. §1927(g)(2)(D) of the Social Security Act, 42 U.S.C. §1396r-8(g)(2)(D).

91 Commentary: HEDIS measures are included in these specifications because they include versions adapted to characteristics of Medicaid populations, e.g., use of an appropriate denominator that is adjusted for discontinuities in Medicaid eligibility. The services to be measured may change from time to time; information on current HEDIS measures is available at www.ncqa.org.

92 Commentary: One option would be to require use of a condition-specific HEDIS outcome measure for a disease management program for the same condition.
§205. Data Collection and Reporting

(a) Maintenance of Pharmaceutical Data System\(^{93}\) — Contractor shall maintain on an ongoing basis an automated pharmaceutical claims processing and information retrieval system that is capable of:

(1) receiving pharmaceutical provider claims;

(2) providing accurate and timely data;

(3) transmitting prescription claims data (including detailed individual enrollee encounter data) electronically:

   (A) to Purchaser's DUR, in the format specified by Purchaser; and

   (if applicable: (B) to [drafter insert name of statewide health insurance claims clearinghouse] in the format specified by clearinghouse);\(^{94}\)

(4) receiving data from:

   (A) Purchaser’s DUR program; and

   (if applicable: (B) to [drafter insert name of statewide health insurance claims clearinghouse]); and

(5) developing practice profiles of providers participating in Contractor's provider network who prescribe pharmaceuticals and providers who dispense pharmaceuticals and patient profiles that are:

   (A) based on drug use review data collected by Contractor and data from Purchaser’s Drug Use Review program [and, if applicable, drafter insert name of a publicly-financed statewide health insurance claims clearinghouse]; and

   (B) are sufficient to provide information as to the use of pharmaceuticals covered under this Agreement.

(b) Collection of Coverage Determinations and Drug Substitution Data — Contractor shall collect data specified in paragraphs (1)-(5) during [purchaser specify

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\(^{93}\) Commentary: This subsection is adapted from federal Medicaid standards for state agency data systems relating to covered benefits, which is referenced as a data system that the state’s Medicaid drug user review/retrospective review of pharmaceuticals may employ. §§1927(g)(2)(B), 1903(r) of the Social Security Act, 42 U.S.C. §§1396r-8(g)(2)(B) and 1396b(r).

\(^{94}\) Commentary: Federal Medicaid law does not address the compatibility of pharmaceutical data claims systems with state insurance clearinghouse claims systems. Drafter may wish to review relevant law in a state that requires all health plans doing business in the state to participate in such a clearinghouse.
data collection period] on the performance of medical necessity and prior authorization decisions and any procedures that result in coverage determinations relating to prescribed pharmaceuticals under this Agreement for each enrollee:

(1) the number of prescriptions (including refills) that were prior authorized;

(2) the number of prescriptions (including refills) for which prior authorization was denied and the reason(s) for denial;

(3) the number of prescriptions for which generic pharmaceuticals were dispensed instead of drugs as prescribed;

(4) the number of prescriptions (if any) for which therapeutically equivalent pharmaceuticals were dispensed instead of drugs as prescribed; and

(5) the number and outcomes of enrollee and provider appeals of denials and restrictions on covered pharmaceuticals.

(c) **Reporting of Data** — Contractor shall submit the following data and reports to Purchaser:

(1) data collected under subsection (b), which shall be submitted [*drafter specify frequency of submission*];

(2) the annual report of the activities of the drug use review program under §204(a)(6), which shall address:

   (A) the nature and scope of Contractor’s drug use review program;

   (B) a summary of the interventions used;

   (C) an assessment of the impact of such interventions on the quality of care; and

   (D) estimated cost savings resulting from such programs;

(3) data on the performance of Contractor’s retrospective drug use review program under §204(a) which shall be submitted [*drafter specify frequency of submission*] and which shall include data on:

   (A) the individual drugs or classes of drugs that were reviewed;

   (B) the number of drug claims that were evaluated;
(C) the interventions that were instituted; and

(D) the results of such interventions;

(4) data collected by Contractor on its performance with regard to any HEDIS measure(s) under §204(b) relating to pharmaceutical therapy used in Contractor’s quality measurement and improvement program, which shall be submitted [drafter specify frequency of submission]; and

(5) data on the extent to which Contractor achieves the goal(s) of any disease management program used by Contractor, which shall be submitted [drafter specify frequency of submission].

§206. Information for Providers

(a) General Rule — Contractor shall provide the information described in this section to providers participating in Contractor’s provider network who prescribe and dispense covered pharmaceuticals as follows:

(1) the information provided to enrollees under §104(a)(1);

(2) information on Contractor’s drug formulary, if any, under §105(b)(1), including:

(A) an explanation of the formulary including the implications of the formulary for enrollee access to covered pharmaceuticals [and, if applicable, the possibility that a formulary pharmaceutical may be subject to prior authorization];

(B) the identity of covered pharmaceuticals or classes of pharmaceuticals that are included in Contractor’s formulary, of which information shall be provided at least annually;

(C) immediate notice of additions to or exclusions from the formulary, including formulary alternatives for excluded pharmaceuticals; and

(D) an explanation of procedures for individual providers to recommend inclusion of a pharmaceutical in Contractor’s formulary;

(3) information on Contractor’s standards and procedures for medical necessity decisions under §105(a), prior authorization procedures, if any, under §105(b)(2), and any other procedures resulting in decisions on an enrollee’s coverage of a pharmaceutical, including:
(A) an explanation(s) of the standards and procedures identified in paragraph (2) and their implications for enrollee access to covered pharmaceuticals;

(B) the identity of covered pharmaceuticals or classes of pharmaceuticals that are subject to prior authorization, of which information shall be provided at least annually;

(C) immediate notice of additions to or exclusions from the list of pharmaceuticals subject to prior authorization;

(D) an explanation of procedures for individual providers to appeal an adverse coverage determination, on behalf of an enrollee; and

(E) an explanation of procedures for individual providers to recommend inclusion or exclusion of a pharmaceutical from prior authorization or other coverage decision-making;

(4) an explanation of the drug use review program under §204(a);

(5) an explanation of any disease management program (as defined in §106(a)(5)) used by Contractor including information about enrollees eligible for such programs, activities of such programs, and provider financial or other incentives available through the program; and

(6) the subject, source and sponsorship of any clinical guidelines and/or practice standards and disease management programs (as defined in §106(a)(5)) that are used by Contractor, Contractors’ subcontractors or any other persons or entities to which Contractor has delegated any of its duties under this Agreement.

(b) Certification of Provision of Information to Providers — Contractor annually shall certify to Purchaser and provide documentation that the information described in subsection (a) has been delivered to providers participating in Contractor's provider network.

§207. Submission of Materials to Purchaser

(a) General Rule\textsuperscript{95,96} — Contractor shall make available to Purchaser at least

\textsuperscript{95} Commentary: This section, adapted from a state Medicaid managed care contract and other CHSRP specifications, is intended to allow the Purchaser to understand how the Contractor is informing its network providers of duties created by the Purchasing Agreement. Because Contractor is expected to have developed these materials as internal management tools, submission at the request of the Purchaser is not expected to be unduly burdensome.

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annually the most recent version of the following information:

(1) Contractor’s provider manual and any other directive, guideline, or protocol which is transmitted by Contractor to providers of pharmaceuticals and pharmaceutical services covered under §103(a) and (b) which relates to the furnishing of such services;

(2) the subcontract(s) and other written agreement(s) between Contractor and providers participating in Contractor’s provider network or other person or entity to which Contractor has delegated one or more of its duties under this Agreement;

(3) Contractor’s operations manual and any other directive, guideline, protocol or other materials setting forth the standards and procedures used by Contractor relating to coverage determinations under §105;

(4) the composition of Contractor’s pharmacy and therapeutics committee;

(5) the written enrollee information described in §104;

(6) a description of any disease management program (as defined in §106(a)(5)) used by Contractor, including:

   (A) practice guidelines used (if any);

   (B) outcomes sought by the program;

   (C) types of activities provided by the program;

   (D) specific pharmaceuticals (if any) used or recommended for use in the program; and

   (E) criteria and procedures for selection of patients to participate in the program;

(7) [drafter describe information on any financial or professional incentives or disincentives relating to usage of specific pharmaceuticals under the Agreement and to the extent that such information is considered to be proprietary; describe Purchaser procedures for preventing disclosure of such information].

96 Commentary: Another option would be to require Contractor to submit one or more of the materials identified in this section to Purchaser for review and approval. Certain Medicaid managed care contracts require, for example, Purchaser approval of a Contractor’s drug formulary, drug use review program standards or other materials. See Repasch and Wehr, supra.

97 Commentary: For a discussion of incentives and their disclosure, see supra, Commentary 35.
(8) the names, practice sites (including zip code(s), hours of business and [drafter insert any other provider information]) of providers participating in Contractor's provider network furnishing pharmaceuticals and pharmaceutical services; and

(9) the composition of Contractor’s drug use review board described in §204(a)(1).

(b) **Notice to Purchaser of Modifications in Certain Materials** — In the case that Contractor, subcontractor or other person or entity to which Contractor delegates any of its duties under the Agreement modifies the contents of any of the materials identified in subsection (a), Contractor shall, at least [drafter insert time period] before the modification takes effect, notify Purchaser and provide copies of the modified materials.