

term care facilities, as well as the way in which they process claims, it would be impracticable for these pharmacies to provide beneficiaries with information regarding covered Part D drug price differentials at the point of sale.

Although long-term care network pharmacies would be exempt from the requirement that information about lower-priced generic alternatives be provided at the point of sale, they would not be exempt from the public disclosure requirement in § 423.132(a) altogether. We request comments regarding appropriate standards with regard to the timing of such disclosure by long-term care pharmacies to the institutionalized Part D enrollees they service. We note, as well, that under § 423.132(d)(2) of our proposed rule, we may modify the timing of the public disclosure requirement under such other circumstances as we deem compliance with that requirement to be impossible or impracticable.

8. Privacy, Confidentiality, and Accuracy of Enrollee Records (§ 423.136)

To the extent that the prescription drug plan offered by a PDP sponsor maintains medical records or other health information regarding Part D enrollees, § 423.136 of our proposed rule would require the PDP sponsor to meet the same requirements regarding confidentiality and accuracy of enrollee records as MA organizations offering MA plans must currently meet under 42 CFR 422.118, according to the stipulations of section 1860D-4(i) of the Act. PDP sponsors would therefore be required to—

- Abide by all Federal and State laws regarding confidentiality and disclosure of medical records or other health and enrollment information, including the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and the privacy rule promulgated under HIPAA;

- Ensure that medical information is released only in accordance with applicable Federal or State law;
- Maintain the records and information in an accurate and timely manner; and
- Ensure timely access by enrollees to records and information pertaining to them.

Prescription drug plans would be considered covered entities under the HIPAA Privacy Rule because they meet the definition of “health plan,” as described in 45 CFR 160.103. The HHS Office for Civil Rights (OCR) is responsible for implementing and enforcing the HIPAA Privacy Rule. OCR has authority to investigate complaints,

to conduct compliance reviews, and to impose civil money penalties for HIPAA Privacy Rules violations. Thus, any violations by an endorsed sponsor with respect to its obligations under the Privacy Rule as a covered entity are subject to such enforcement by OCR. OCR maintains a Web site with frequently asked questions and other compliance guidance at <http://hhs.gov/ocr/hipaa>.

D. Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans

1. Overview (§ 423.150)

Subpart D of part 423 implements provisions included in sections 1860D-4(c), 1860D-4(d), 1860D-4(e), 1860D-4(j), and 1860D-21(d)(3) of the Act and sections 102(b) and 109 of Title I of the MMA. This subpart sets forth the following requirements:

- Cost and Utilization Management Programs, Quality Assurance Programs, Medication Therapy Management Programs (MTMP), and Programs to control fraud, abuse, and waste for PDP sponsors and MA Organizations offering MA-PD plans that offer qualified prescription drug coverage;
 - CMS consumer satisfaction surveys of PDP and MA-PD plan enrollees.
 - Electronic prescription programs.
 - Compliance deemed on the basis of accreditation.
 - Accreditation organizations.
 - Procedures for the approval of accreditation as a basis for deeming compliance.

2. Cost and Utilization Management, Quality Assurance, Medication Therapy Management, and Programs To Control Fraud, Abuse, and Waste (§ 423.153)

Section 423.153(a) of our proposed rule would require each PDP sponsor or MA Organization offering a MA-PD plan that provides qualified prescription drug coverage under a prescription drug plan to establish a cost-effective drug utilization management program, a quality assurance program, a MTMP, and a program to control fraud, abuse, and waste as described in §§ 423.153(b), 423.153(c), 423.153(d), and 423.153(e), respectively.

We have combined these requirements into one section of the proposed regulation because each of these requirements would impact the quality and cost of care provided to beneficiaries. Our intent is to ensure that the prescription drug benefit would be provided using state of the art cost management and quality assurance systems. We also understand the overlapping nature of these

requirements and that provisions under one requirement might complement another requirement. For example, drug utilization management early-refill edits used to prevent stockpiling of medications could also identify potential medication misuse by patients.

Although these requirements are similar in their underlying goals, they can also be quite different. For example, drug utilization management and quality assurance systems are generally considered to be population based, while medication therapy management involves targeted, direct patient care.

While we understand that some members of industry use various quality assurance measures and systems for controlling utilization and reducing medication errors, less information is available regarding medication therapy management. Medication therapy management has been used to describe a broad range of professional activities and responsibilities. We are familiar with state Medicaid programs (for example, Wisconsin, Mississippi) paying for cognitive services as part of their prescription drug benefit, but we have less information about current similar practices in the private sector. Therefore, our regulatory approach for utilization management, quality assurance, and controlling fraud, abuse, and waste will be different than our approach for medication therapy management. We particularly ask for comments on this section of the proposed regulation.

In general, and within the parameters described later in this preamble and in regulation, PDP sponsors and MA Organizations offering MA-PD plans would have flexibility to design drug utilization management programs, quality assurance measures and systems, MTMPs, and programs designed to control fraud, abuse, and waste.

a. Cost Effective Drug Utilization Management

Section 423.153(b) of our proposed rule would require each PDP sponsor or MA Organization offering a MA-PD plan that provides qualified prescription drug coverage under a prescription drug plan to provide a cost-effective drug utilization management program. The program would include incentives to reduce costs when medically appropriate, such as through the use of multiple source drugs as defined in section 1927(k)(7)(A)(i) of the Act. For example, plans could utilize different dispensing fees that would encourage the use of these multiple source drugs as opposed to more expensive single source drugs. This should not be

confused with the practice of “switching” one branded drug product with another similar branded drug product, commonly referred to as “therapeutic substitution.” Therapeutic substitution would always require explicit prescriber notification and approval.

We believe that a cost-effective drug utilization management program could also employ the use of prior authorization, step therapy, tiered cost-sharing, and other tools to manage utilization. We are aware that these are tools commonly used today to manage pharmacy benefit costs for many commercial and State programs. We believe that the competitive bidding and premium setting processes, combined with the requirements for transparency and information availability, provide powerful incentives for plans to innovate and adopt the best techniques available. We invite comment on whether there are industry standards for cost effective drug utilization management and whether CMS should adopt any of these standards for PDPs and MA-PDs.

Although we have not included proposed regulations, we are considering for the final rule a requirement that these tools should be under the direction and oversight of a Pharmacy and Therapeutics Committee to ensure an appropriate balance between clinical efficacy and cost effectiveness. We seek comments on this issue. We also seek comments on requiring the direct involvement of a Pharmacy and Therapeutics Committee not only with cost containment measures, but also with other areas of quality assurance and medication therapy management. Again, although we have not included proposed regulations requiring this standard, we are considering this standard for our final rule.

In addition, appropriate drug utilization management programs would have policies and systems in place to assist in preventing overutilization and underutilization of prescribed medications. PDP sponsors and MA Organizations offering MA-PD plans must inform enrollees of program requirements and procedures in order to prevent unintended interruption in drug therapy. For example, enrollees would be made aware of how to proceed if special circumstances require their prescriptions to be refilled before the targeted refill date.

b. Quality Assurance

Section 423.153(c) of our proposed rule would require each PDP sponsor or MA Organization offering a MA-PD

plan that provides qualified prescription drug coverage under a prescription drug plan to provide a quality assurance program. That program would include quality assurance measures and systems for (1) reducing medication errors, (2) reducing adverse drug interactions, and (3) improving medication use.

We are proposing that quality assurance programs include requirements for drug utilization review, patient counseling, and patient information record-keeping. We believe these requirements would generally need to comply with section 4401 of the Omnibus Reconciliation Act of 1990 as codified in 42 CFR 456.705 and section 1927(g)(2)(A) of the Act, and we are considering such specific requirements for the final rule. Although these regulations were written specifically for the Medicaid population, we understand that they describe currently accepted standards for contemporary pharmacy practice and our intent is to require plans to continue to comply with contemporary standards. We solicit comment on whether the Medicaid standards are in fact industry standards, whether they are appropriate standards for part D, and if they are, how they should be adapted for use in part D. Therefore, we have chosen not to add further specification in the regulation text. We also understand that some members of industry use additional quality assurance measures and systems. We invite comments on whether there are industry standards, above and beyond those mentioned above, that we might adopt. Furthermore, PDP sponsors and MA Organizations offering MA-PD plans will be required to have systems and measures established to ensure that network pharmacy providers are complying with their quality assurance requirements. We are requesting comments on the costs and challenges associated with these systems and measures.

The elements that are currently viewed as desirable for quality assurance systems are—(1) electronic prescribing (which will become a requirement in the future as discussed later in this preamble); (2) clinical decision support systems; (3) educational interventions, which could be provided by QIOs or could rely on other mechanisms; (4) bar codes; (5) adverse event reporting systems; and (6) provider and patient education. We do not expect PDPs and MA-PD plans to adopt all of these elements. However, we expect substantial innovation and rapid development of improved quality assurance systems in the new competitive and transparent market

being created by the new Part D benefit. We invite comments on which, if any, elements of a quality assurance system should be contained in our program requirements. We are particularly interested in best practices in quality assurance, costs and benefits associated with each element, the challenges involved in implementing quality assurance measures and systems, types of data useful for reducing medication errors, associated costs and challenges with collecting this data, and how this data could be best communicated to providers and beneficiaries to improve medication use.

We note that the MMA does not define or explain the term “medication error.” Nevertheless, we believe a common definition is important. In the future, we may require quality reporting that includes error rates. We could use this information to evaluate plans. In addition, we may publish this information for enrollees to use when comparing and choosing their individual plans. Therefore, we particularly invite comments on how we could evaluate PDPs and MA-PDs based on the types of quality assurance measures and systems they have in place, how error rates can be used to compare and evaluate plans, and how this information could best be provided to beneficiaries to assist them in making their choices among plans.

Medication error reduction programs and requirements have been discussed in many venues and various definitions of “medication error” have been used. For example, in its proposed rule requiring bar codes on most human drug products, the Food and Drug Administration adopted the following definition of a medication error:

Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice; healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use. (*See* 68 FR 12500 (March 14, 2003)).

This definition of “medication error” is identical to that used by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). (*See* National Coordinating Council for Medication Error Reporting and Prevention, “What is a Medication Error?” (Undated)).

We are citing this definition in this preamble as one that we would use initially in interpretive guidance. We believe that this definition could be

applied to, and include, adverse drug events and interactions as they pertain to quality assurance. As the state of industry practice evolves, we may, from time to time, update this definition by manual issuance. We invite comments on this definition.

c. Medication Therapy Management Programs

Section 1860D–4(c)(1)(C) of the Act requires PDP sponsors and MA organizations offering MA–PD plans to establish a MTMP, and § 423.153(d) would codify that requirement. As stated earlier, neither we, nor many private insurers, have extensive experience requiring or reimbursing for MTMPs. As a result, we seek comments on what requirements and/or guidelines for MTMPs should be formulated in our regulation. In this section of the preamble, we are providing a broad overview of the types of activities that a PDP sponsor or MA organization offering a MA–PD plan could provide as part of a MTMP. We also discuss various options for determining which beneficiaries might qualify as “targeted individuals” and what types of clinicians might provide MTMP services. We plan to conduct further research and seek comments before establishing requirements with respect to MTMPs. We are interested in current MTMP best practices, essential components of MTMPs, and which quality assurance requirements, if any, should be included in MTMPs. We are also interested in measures and information on effective MTMP services that could be publicized and used by beneficiaries who wish to use these services. We are particularly interested in the most effective steps to make valuable, proven MTMP services available to beneficiaries to improve health care quality and reduce costs. We are mindful of the importance of stimulating the evolution of the most appropriate and efficient form of MTMPs, without stifling innovation or prematurely locking-in specific attributes.

The description of a MTMP in section 1860D–4(c)(2) of the Act would allow for plans to establish a broad range of additional services. The purpose of a MTMP is to provide services that will optimize therapeutic outcomes for targeted beneficiaries. Specific services to be provided under a MTMP would be distinct from those required for dispensing medication. Medication therapy management services would be reimbursable when adopted by a plan and only when provided to targeted beneficiaries as defined in § 423.153(2)

of our proposed rule and discussed later in this preamble.

Section 1860D(4)(c)(2)(B) of the Act states that MTMPs may include elements designed to promote (for targeted beneficiaries):

- Enhanced enrollee understanding—through beneficiary education counseling, and other means—that promotes the appropriate use of medications and reduces the risk of potentially adverse events associated with the use of medications.
- Increased enrollee adherence to prescription medication regimens (for example, through medication refill reminders, special packaging, and other compliance programs and other appropriate means).
- Detection of adverse drug events and patterns of overuse and underuse of prescription drugs.

In order to promote these elements and optimize therapeutic outcomes for targeted beneficiaries, we envision MTMPs potentially spanning a range of services, from simple to complex. In addition to those mentioned in the statute, services could include, but not be limited to, performing patient health status assessments, formulating prescription drug treatment plans, managing high cost “specialty” medications, evaluating and monitoring patient response to drug therapy, providing education and training, coordinating medication therapy with other care management services, and participating in State-approved collaborative drug therapy management. We would also anticipate that these services could be offered as components of more coordinated disease management programs, but would not expect provision of these services to be limited to such programs.

In addition to MTMPs providing for different types of services, we would also anticipate the need for different levels of service based on the individual requirements of targeted beneficiaries. For example, one beneficiary may require only a fifteen-minute phone consultation, while another would be better served by a one-hour in-person visit with the pharmacist. The level of service should be determined by time and resources required to accommodate the specific needs of the individual beneficiary. Therefore, we would anticipate that a MTMP would include policies and procedures for ensuring targeted beneficiary access to the appropriate types and levels of service offered by the particular PDP or MA–PD plan.

Within this broad framework, we believe that PDP sponsors and MA Organizations offering MA–PD plans

can customize their MTMPs and that a competitive market supported by useful information on MTMP services will provide the best mechanism for establishing optimal MTMPs. We believe that MTMPs can lead to improved overall health for individuals, while at the same time decreasing overall healthcare costs resulting from improper medication use and adverse drug events. We may provide a mechanism for plans to demonstrate the types of services, levels of service, and quality outcomes associated with their MTMPs to further aid beneficiaries with choosing the plan that will best meet their needs.

In addition, as provided in § 423.153(d)(3), a MTMP, as adopted by a plan, would have to be developed in cooperation with licensed practicing pharmacists and physicians.

Beyond these broad parameters for a MTMP, there are several issues to consider as we provide additional guidance to PDP sponsors and MA organizations. First, we consider MTMPs to be administrative activities similar to quality assurance drug utilization review or measures to control fraud, abuse and waste. Like these other quality improvement services intrinsic to the drug plan, MTMP services would not involve direct beneficiary cost-sharing and Part D enrollees would not be required to pay separate fees for these services (although the cost could be reflected in the premium rate). The cost of a MTMP is considered an administrative cost incident to appropriate drug therapy and, therefore, not an additional benefit. Nevertheless, unlike the general quality assurance and fraud, abuse, and waste control requirements, MTMP services can be limited to targeted beneficiaries. To the extent that MTMPs reduce drug spending by more than their costs, they have the potential to lower overall Part D costs. To the extent that MTMP services lower overall medical costs for beneficiaries with chronic illnesses, we also seek comment on how to integrate MTMP services and financial incentives into the Medicare Chronic Care Improvement program (section 721 of the Act).

Second, section 1860D4(c)(2)(A)(ii) of the Act requires that MTMP services be provided only for targeted individuals. In other words, not all members of a plan would be entitled to receive these services. As provided under § 423.153(d)(2), “targeted beneficiaries” would be plan enrollees who have multiple chronic diseases, are taking multiple Part D covered drugs, and are likely to incur annual costs that exceed a certain level that we determine. We

invite comments on how we should provide guidance to drug plans in defining “multiple chronic diseases” and “multiple covered Part D drugs” for the purposes of determining which Part D enrollees would qualify for MTMP services, or whether such determinations are best left to the plans as part of their benefit design.

While the statute states that CMS sets the level of annual costs that must be incurred by a beneficiary to qualify for the receipt of MTMP services, our preferred policy is to delegate this function to the private drug plans, as they would be able to evaluate their patients with greater specificity and information. We request comments on this policy as both a policy and legal matter. We believe that, given current evidence, the level of annual costs that must be incurred by a beneficiary to qualify for the receipt of MTMP services should be determined by the drug plan. We do not think there is sufficient evidence at this point to specify a threshold of annual drug costs to be used for targeting these services to particular Part D enrollees. However, we seek comments on what guidance we could provide to plans to ensure these services are targeted in the most efficient manner and to the most appropriate beneficiaries.

In addition, we are concerned about the method that plans should use to determine the costs that enrollees are “likely to incur” to ascertain whether they qualify as targeted beneficiaries. Once plans have historical data on specific patients, determining how to target such services should become easier and more effective. For example, based on their previous experience with providing prescription drug services, plans could qualify enrollees for MTMP services based on whether the enrollees have multiple chronic diseases and whether they are using multiple drugs. As they develop more experience with their Medicare enrollees, past medication history might become another useful guide.

We believe that plans would benefit from additional guidance on interpreting the level above which a beneficiary’s incurred costs would qualify him or her for MTMP services. We invite comments on all the disease, drug, and cost issues that we should consider in further refining the definition of a targeted beneficiary for receipt of MTMP services.

Another issue to be considered relates to which clinicians would be providing MTMP services and the method for providing those services. Section 1860D–4(c)(2)(A)(i) of the Act specifically states that a pharmacist may

furnish MTMP services. While we believe that pharmacists will be the primary providers of these services, MTMPs could also include other qualified health care professionals as providers of services. The individual needs of the targeted beneficiary should determine the appropriate provider and setting for MTMP services. For example, consultant pharmacists will likely provide services to beneficiaries in long-term care facilities; retail pharmacists could provide those same services to ambulatory beneficiaries.

Furthermore, we believe beneficiary choice and on-going beneficiary-provider relationships should play a role in determining the best provider for MTMP services. Improved therapeutic outcomes through MTMP services will frequently require active beneficiary, or caregiver, participation. While population based quality assurance and cost control measures might adequately be served by impersonal telephone services, we believe that telephone services are only one mode of providing medication therapy management services. Active beneficiary participation and consistent delivery of quality MTMP services will require developing and maintaining on-going beneficiary-provider relationships. Therefore, to the extent that these services are adopted by plans in their MTMPs, we would expect the range of services offered to reflect this important component and maximize beneficiary participation by considering beneficiary preference and existing beneficiary-provider relationships in determining the appropriate provider and setting for delivery of MTMP services.

Section 1860D–4 (c)(2)(E) of the Act states that in establishing fees for pharmacists or others providing MTMP services, to the extent that these services are adopted by a plan in its MTMP, a PDP sponsor must take into account the resources and time associated with implementing the MTMP. Section 423.153(d)(5) codifies that requirement. We propose to implement this requirement as follows:

(1) First, we would expect potential PDP sponsors to describe, as part of their applications, their plan to consider the resources used and the time required to implement their MTMP in establishing fees for pharmacists and others providing services under the MTMPs.

(2) Second, in the event that we receive complaints that a PDP sponsor is not paying pharmacists or others in accordance with the fees discussed in the application for the MTMP it has elected to adopt, we would investigate further.

While section 1860D–4(c)(2)(E) of the Act specifies that the time and resources necessary to implement the MTMP must be taken into account when establishing fees, it does not specify how these fees should be paid. We believe that fees associated with provision of medication therapy management services are separate and distinct from dispensing fees discussed in section § 423.100 of the preamble for this proposed regulation. Although section 1860D–4(c)(2)(E) of the Act states that PDP sponsors must disclose to the Secretary the amount of “any such management or dispensing fees”, it merely governs disclosure and does not require that MTMP be included in the dispensing fee (indeed the Act distinguishes management fees from dispensing fees that are part of individual prescriptions).

Therefore, costs associated with MTMPs, including these management fees, are included as part of the general administrative overhead costs in the plan bid. For purposes of evaluating the administrative component of a PDP’s bid, we will ask a PDP sponsor or MA organization to disclose the fees it pays to pharmacists or others, including an explanation of those fees attributable to MTMP services. The fee information provided to us under this authority would be protected under the confidentiality provisions of section 1927(b)(3)(D) of the Act. Under those provisions, we would be prohibited from disclosing the specific fees in a manner that links the fees to the particular pharmacy or other provider providing the MTMP services—except to the extent necessary to administer the Part D program, to permit the Comptroller General to review the information, or to permit the Director of the Congressional Budget Office to review the information. If we were to discover situations in which plans systematically did not pay the fees described in their applications—and, if those errors were not corrected upon notification, we might, at our discretion, employ the broad ranges of intermediate sanctions or termination provisions available under subparts K and O of the regulations.

While we expect to perform the due diligence described above through application review and potentially following up on any complaints we do not believe we have the authority to mandate that PDP sponsors or MA organizations pay pharmacists or other providers a certain amount for MTMP services. We also would not adjudicate any specific disputes between PDP sponsors or MA organizations and pharmacists or other providers

regarding the specific fees due for MTMP services.

Finally, as specified in section 1860D-4(c)(2)(D) of the Act, we are required to establish guidelines that MTMPs operated by PDP sponsors are coordinated with the "chronic care improvement program" (CCIP) under section 1807 of the Act. The CCIP is a new program established by section 721 of the MMA, which added a new section, section 1807, to the Act. The new section 1807 creates a method for us to assist beneficiaries with multiple chronic conditions in managing their care. The program is targeted only to beneficiaries in original fee-for-service Medicare—not beneficiaries enrolled in MA plans. Therefore, we anticipate that our guidelines will be targeted toward PDP sponsors and not to MA organizations that offer MA-PD plans. As stated above, the CCIP is a new program. By statute, the first agreements under that program with chronic care improvement organizations should be entered into within 12 months of the MMA's date of enactment. On April 23, 2004, we published in the **Federal Register** (69 FR 22065-22079), the solicitation for the CCIP program. Because the program has not yet been established, however, we cannot provide a great deal of guidance at this time regarding how the MTMPs under Part D would coordinate with the CCIP. We are concerned with the possibility of beneficiaries receiving duplicative services. We seek comments on how MTMP services provided through CCIP can be effectively coordinated with MTMP services provided by PDPs. There are several different ways that communication could take place so that a beneficiary enrolled in both the CCIP and a PDP receives efficient assistance with managing their chronic diseases. For example, the CCIP might collect information at intake, obtain a beneficiary information release, and inform the PDP of enrollment. An alternate approach is for us to use the enrollment files from the two programs to communicate to the respective parties. We invite comments on this issue and these proposed options. We may provide further interpretive guidance on coordination with the CCIP once the section 1807 agreements are finalized and the new program is in place. We invite comments from interested parties relating to specific key issues that should be addressed in this guidance.

d. Fraud, Abuse and Waste

Section 423.153(e) of our proposed rule would require PDP sponsors and MA Organizations offering MA-PD

plans that provide qualified prescription drug coverage under a prescription drug plan to provide a program to control fraud, abuse, and waste. These requirements overlap to some extent with those in subpart K of this regulation, but cover somewhat different territory.

We would expect these plans, as prudent purchasers, to implement programs to control their expenditures. We would be interested in comments on the following discussion as to possible requirements in this area over and above the incentives operating in at risk plans. We would also like comments on the value added from requiring plans to develop comprehensive performance standards for use in evaluating internal processes that would appropriately and efficiently research, identify, monitor, and take immediate action to mitigate fraud, abuse, and waste. Fraud, abuse, and waste apply not only to both the PDPs and MA-PDs and their staffs, but also to the PBMs, pharmacies, physicians, and other providers that they deal with. For instance, PDPs and MA-PDs need to determine whether or not physicians are illegally prescribing narcotics. In addition to available appropriate data that might be supplied by us, the plans could develop and utilize methods such as data analysis, record audit of PBMs, pharmacies, physicians, and other providers, DUR (note these DURs overlap with those described previously, but these focus on those related to fraud, abuse, and waste), and methods used to consider and resolve disputes related to pharmacies, physicians', and other provider's dissatisfaction to ensure the integrity of all entities (government, beneficiary, PDP sponsor, PBMs, pharmacies, physicians, and other providers).

One area of concern is inappropriate switching of prescriptions by a PDP or MA-PD plan without consulting a prescribing physician. For instance, switching from brand to generic may be appropriate, but switching brands, *e.g.* Lipitor to Zocor, may not without consultation.

We also seek comments on the appropriateness, value and need for requiring the plans to test program integrity analytic tools for effectiveness, efficiency, and adaptability to the Medicare Benefit environment. For example, one approach could require the plans to provide any of the following in periodic reports: (1) Summary of data analysis activities, (2) resources, (3) tools, or (4) trend analysis. Alternatively, the plans could be required to develop their strategy and propose what each plan determines to

be the best approach for detecting and deterring fraud and abuse. Furthermore, the plans could be asked to demonstrate that the agreed upon activities and outcomes that the plans achieve are in relation to priorities established by us. We seek comments on the likely value of these requirements. We also seek comments on the implementation, scope, and operation of an effective and robust fraud, abuse, and waste control program for plan sponsors.

e. Exception for Private Fee for Service Plans

Section 423.153(f) of our proposed rule would implement section 1860D-421(d)(3) of the Act by exempting private fee-for-service MA plans that offer qualified prescription drug coverage from the requirement to establish a drug utilization management program and a MTMP; however, these private fee-for-service MA plans would still be required to establish a quality assurance program and program to control fraud, abuse and waste as described in § 423.153(c) and § 423.153(e), respectively.

3. Consumer Satisfaction Surveys (§ 423.156)

Under § 423.156, we would conduct consumer satisfaction surveys among enrollees of PDPs and MA Organizations offering MA-PD plans in order to provide comparative information about qualified prescription drug coverage to enrollees as part of our information dissemination efforts. Section 1860D-4(d) of the Act specifies that these surveys be conducted in a manner similar to that in which they are currently conducted under § 422.152(b) (that is, annually) for MA plans by using the Consumer Assessment of Health Plans (CAHPS). We believe a CAHPS-like instrument (or perhaps a modification of CAHPS for MA Organizations offering MA-PD plans) will most likely be the vehicle used to collect this information. As we have done in the past in developing surveys of Medicare beneficiaries in various settings, we will work with the Agency for Healthcare Research and Quality (AHRQ) to develop a survey measuring the experience of beneficiaries with their qualified prescription drug coverage, a sampling strategy, and an implementation strategy. We will provide further information regarding this survey as it is developed.

4. Electronic Prescription Program (§ 423.159)

Section 1860D-4(e) of the Act contains provisions for electronic prescription programs. The statute

(6) Coverage under a Medicare supplemental policy (Medigap policy) under section 1882 of the Act, and as specified in 42 CFR 403.205, that provides prescription drug benefits, whether or not the coverage was issued pursuant to standardization requirements under section 1882(p)(1) of the Act.

(7) Military coverage under chapter 55 of title 10, U.S.C., including TRICARE.

(8) Individual health insurance coverage (as defined in section 2791(b)(5) of the Public Health Service Act) that includes coverage for outpatient prescription drugs and that does not meet the definition of an excepted benefit (as defined in section 2791(c) of the Public Health Service Act).

(9) Coverage provided by the medical care program of the Indian Health Service, Tribe or Tribal organization, or Urban Indian organization (I/T/U).

(b) *General.* With the exception of PDPs and MA-PD plans under 423.56(a)(1), each entity that offers prescription drug coverage under any of the types described in § 423.56(a), must disclose to all Part D eligible individuals enrolled in or seeking to enroll in such coverage whether such coverage meets the requirements of actuarial equivalence of § 423.265.

(c) *Disclosure of non-creditable coverage.* In the case that the coverage does not meet the actuarial equivalence requirements at § 423.265 the disclosure described in paragraph (b) of this section to Part D eligible individuals must include:

(1) The fact that the coverage does not meet the actuarial equivalence requirement under 423.265;

(2) That there are limitations on the periods in a year in which the individual may enroll under a PDP or MA-PD plan; and

(3) That the individual may be subject to a late enrollment penalty, under § 423.46.

(d) *Disclosure to CMS.* Each entity must disclose the creditable coverage status to CMS in a form and manner described by CMS.

(e) *Notification.* Notification to Part-D eligible individuals must be provided in a form and manner prescribed by CMS.

(f) *When an individual is not adequately informed of coverage.* If an individual establishes to CMS that he or she was not adequately informed that his or her prescription drug coverage was not creditable, the individual may apply to CMS to have such coverage treated as creditable coverage for purposes of applying § 423.46.

Subpart C—Benefits and Beneficiary Protections.

§ 423.100 Definitions.

As used in this subpart, unless otherwise specified—

Alternative prescription drug coverage means coverage of covered Part D drugs other than standard prescription drug coverage that meets the requirements of § 423.104(f). The term “alternative prescription drug coverage” must be either—

(1) *Basic alternative coverage* (alternative coverage that is actuarially equivalent to defined standard coverage), as determined through processes and methods established under § 423.265; or

(2) *Enhanced alternative coverage* (alternative coverage that meets the requirements of § 423.104(g)(1)).

Basic prescription drug coverage means coverage of covered Part D drugs that is either standard prescription drug coverage or basic alternative coverage.

Bioequivalent has the meaning given such term in section 505(j)(8) of the Food, Drug, and Cosmetic Act.

Covered Part D drug means—

(1) Unless excluded under number (2) of this definition, any of the following if used for a medically accepted indication (as defined in section 1927(k)(6) of the Act)—

(i) A drug that may be dispensed only upon a prescription and that is described in sections 1927(k)(2)(A)(i) through (iii) of the Act;

(ii) A biological product described in sections 1927(k)(2)(B)(i) through (iii) of the Act;

(iii) Insulin described in section 1927(k)(2)(C) of the Act;

(iv) The following medical supplies associated with the injection of insulin: syringes, needles, alcohol swabs, and gauze; or

(v) A vaccine licensed under section 351 of the Public Health Service Act.

(2) Does not include—

(i) Drugs for which payment as so prescribed and dispensed or administered to an individual is available with respect to that individual under Parts A or B (even though a deductible may apply, or even though the individual is eligible for coverage under Parts A or B but has declined to enroll in Parts A or B); and

(ii) Drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid pursuant to sections 1927(d)(2) or (d)(3) of the Act, except for smoking cessation agents.

Group health plan has the meaning given such term in § 411.101 of this chapter.

Incurred costs means costs incurred by a Part D enrollee for covered part D drugs covered under (or treated as covered under) a prescription drug plan or MA-PD plan—

(1) That are not paid for under the prescription drug plan or MA-PD as a result of application of any annual deductible or other cost-sharing rules for covered part D drugs prior to the Part D enrollee satisfying the out-of-pocket threshold under § 423.104(e)(5)(iii), including any price differential for which the Part D enrollee is responsible under § 423.120(a)(6) and § 423.124(b)(2); and

(2) That are paid for—

(i) By the Part D enrollee or on behalf of the Part D enrollee by another person, and the Part D enrollee (or person paying on behalf of the Part D enrollee) is not reimbursed through insurance or otherwise, a group health plan, or other third party payment arrangement, or the person paying on behalf of the Part D enrollee is not paying under insurance or otherwise, a group health plan, or third party payment arrangement;

(ii) Under a State Pharmaceutical Assistance Program as described in § 423.454; or

(iii) Under § 423.782.

Insurance or otherwise means a plan (other than a group health plan) or program that provides, or pays the cost of, medical care (as defined in section 2791(a)(2) of the Public Health Service Act, 42 U.S.C. 300gg-91(a)(2)), including any of the following:

(1) Health insurance coverage as defined in 42 U.S.C. 300gg-91(b)(1);

(2) An MA plan as described in § 422.2 of this chapter.

(3) A program of all-inclusive care for the elderly (PACE) under titles XVIII and XIX of the Act;

(4) An approved State child health plan under title XXI of the Act providing benefits for child health assistance that meet the requirements of section 2103 of the Act;

(5) The Medicaid program under title XIX of the Act or a waiver pursuant to section 1115 of the Act;

(6) The veterans health care program under chapter 17 of title 38 of the U.S.C.

(7) Any other government-funded program whose principal activity is the direct provision of health care to individuals.

I/T/U pharmacy means a pharmacy operated by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization, all of which are defined in section 4 of the Indian Health Care Improvement Act, 25 U.S.C. 1603.

Long-term care facility means a skilled nursing facility, as defined in

section 1819(a) of the Act, or nursing facility, as defined in section 1919(a) of the Act.

Long-term care pharmacy means a pharmacy owned by or under contract with a long-term care facility to provide prescription drugs to the facility's residents.

Long-term care network pharmacy means a long-term care pharmacy that is a network pharmacy.

Negotiated prices means prices for covered Part D drugs that—

- (1) Are available to beneficiaries at the point of sale at network pharmacies; and
- (2) Take into account discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remunerations and include any dispensing fees.

Network pharmacy means a licensed pharmacy that is not a mail order pharmacy and that is under contract with a PDP sponsor or MA organization offering an MA–PD plan to provide negotiated prices to its prescription drug plan or MA–PD plan enrollees.

Non-preferred pharmacy means a network pharmacy that offers Part D enrollees higher cost-sharing for covered Part D drugs than a preferred pharmacy.

Out-of-network pharmacy means a licensed pharmacy that is not under contract with a PDP sponsor or MA organization offering an MA–PD plan to provide negotiated prices to its prescription drug plan or MA–PD plan enrollees.

Person means a natural person, corporation, mutual company, unincorporated association, partnership, joint venture, limited liability company, trust, estate, foundation, not-for-profit corporation, unincorporated organization, government or governmental subdivision or agency.

Plan allowance means the amount prescription drug plans and MA–PD plans use to determine their payment and Part D enrollees' cost-sharing for covered Part D drugs purchased at out-of-network pharmacies in accordance with the requirements of § 423.124(b).

Preferred drug means a covered part D drug on a prescription drug plan or MA–PD plan's formulary for which beneficiary cost-sharing is lower than for a non-preferred drug in the plan's formulary.

Preferred pharmacy means a network pharmacy that offers Part D enrollees lower cost-sharing for covered Part D drugs than a non-preferred pharmacy.

Qualified prescription drug coverage means any standard prescription drug coverage or alternative prescription drug coverage that meets the requirements of § 423.104(d).

Required prescription drug coverage means coverage of covered Part D drugs under an MA–PD plan that consists of either—

- (1) Basic prescription drug coverage; or
- (2) Enhanced alternative coverage, provided there is no MA monthly supplemental beneficiary premium applied under the plan due to the application of a credit against the premium of a rebate under § 422.266(b) of this chapter.

Rural means a five-digit ZIP code in which the population density is less than 1,000 individuals per square mile.

Standard prescription drug coverage means coverage of covered Part D drugs that meets the requirements of § 423.104(e). The term "standard prescription drug coverage" must be either—

- (1) *Defined standard coverage* (standard prescription drug coverage that provides for cost-sharing as described in §§ 423.104(e)(2)(i)(A) and (e)(5)(i)); or

- (2) *Actuarially equivalent standard coverage* (standard prescription drug coverage that provides for cost-sharing as described in § 423.104(e)(2)(i)(B) or cost-sharing as described in § 423.104(e)(5)(ii), or both).

Suburban means a five-digit ZIP code in which the population density is between 1,000 and 3,000 individuals per square mile.

Supplemental benefits means benefits that meet the requirements of § 423.104(g)(1)(ii).

Therapeutically equivalent refers to drugs that are rated as therapeutic equivalents under the Food and Drug Administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations."

Third party payment arrangement means any contractual or similar arrangement under which a person has a legal obligation to pay for covered Part D drugs.

Urban means a five-digit ZIP code in which the population density is greater than 3,000 individuals per square mile.

Usual and customary (U&C) price means the price that a pharmacy charges a customer who does not have any form of prescription drug coverage.

§ 423.104 Requirements related to qualified prescription drug coverage.

(a) *General.* Subject to the conditions and limitations set forth in this subpart, a PDP sponsor offering a prescription drug plan or an MA organization offering an MA–PD plan must provide enrollees with coverage of the benefits described in paragraph (c) of this

section. The benefits may be provided directly by the PDP sponsor or MA organization or through arrangements with other entities. CMS reviews and approves these benefits consistent with § 423.272, and using written policy guidelines and requirements in this part and other CMS instructions.

(b) *Availability of plans.* Except as provided in § 422.60(b) of this chapter, a PDP sponsor offering a prescription drug plan must offer that plan to all Part D eligible beneficiaries residing in the plan's service area.

(c) *Types of benefits.* A prescription drug plan or MA–PD plan must include qualified prescription drug coverage.

(d) *Qualified prescription drug coverage.* Qualified prescription drug coverage includes—

- (1) Standard prescription drug coverage consistent with paragraph (e) of this section; or

- (2) Alternative prescription drug coverage consistent with paragraph (f) of this section.

(e) *Standard prescription drug coverage.* Standard prescription drug coverage includes access to negotiated prices as described under paragraph (h)(1) of this section, provides coverage of covered Part D drugs, and must meet the following requirements—

- (1) *Deductible.* An annual deductible equal to—

- (i) For 2006. \$250; or

- (ii) For years subsequent to 2006. The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (e)(5)(iv) of this section, and rounded to the nearest multiple of \$5.

- (2) *Cost-sharing under the initial coverage limit.*

- (i) *25 Percent coinsurance.*

Coinsurance for costs for covered Part D drugs covered under the plan above the annual deductible specified in paragraph (e)(1) of this section, and up to the initial coverage limit under paragraph (e)(3) of this section, that is—

- (A) Equal to 25 percent for defined standard coverage; or

- (B) Actuarially equivalent to an average expected coinsurance of no more than 25 percent, as determined through processes and methods established under § 423.265, for actuarially equivalent standard coverage.

(ii) *Tiered copayments.* A prescription drug plan or MA–PD plan may apply tiered copayments without limit, provided that any tiered copayments are consistent with paragraph (e)(2)(i)(B) of this section and are reviewed as described in § 423.272(b)(2).

- (3) *Initial coverage limit.* The initial coverage limit is equal to—

(iv) *Benefits.* (A) Covered services under the prescription drug plan;

(B) Any beneficiary cost-sharing, such as deductibles, coinsurance, and copayment amounts, including cost-sharing for subsidy eligible individuals;

(C) Any maximum limitations on out-of-pocket expenses;

(D) The extent to which an enrollee may obtain benefits from out-of-network providers;

(E) The types of pharmacies that participate in the prescription drug plan's or MA-PD plan's network and the extent to which an enrollee may select among those pharmacies; and

(F) Out-of-network pharmacy access.

(v) Premiums;

(vi) The prescription drug plan's or MA-PD plan's formulary;

(vii) The prescription drug plan's or MA-PD plan's service area; and

(viii) Quality and performance indicators for benefits under a plan as determined by CMS.

(2) The procedures the PDP sponsor or MA organization offering an MA-PD plan uses to control utilization of services and expenditures.

(3) The number of disputes, and the disposition in the aggregate, in a manner and form described by CMS. These disputes are categorized as—

(i) Grievances according to § 422.564 of this chapter;

(ii) Rights to a reconsideration according to § 422.578 *et. seq.* of this chapter.

(4) Financial condition of the PDP sponsor or MA organization, including the most recently audited information regarding, at a minimum, a description of the financial condition of the PDP sponsor or MA organization offering the prescription drug plan or MA-PD plan.

(d) *Provision of specific information.* Each PDP sponsor or MA organization offering qualified prescription drug coverage must have mechanisms for providing specific information on a timely basis to current and prospective enrollees upon request. These mechanisms must include—

(1) A toll-free customer call center that—

(i) Is open during usual business hours.

(ii) Provides customer telephone service, including to pharmacists, in accordance with standard business practices.

(2) An Internet Website that—

(i) Includes, at a minimum, the information required in paragraph (b) of this section.

(ii) Includes a current formulary for its PDP plan or MA-PD plan, updated at least weekly.

(iii) Provides current and prospective Part D enrollees with at least 30 days

notice regarding the removal or change in the preferred or tiered cost-sharing status of a covered Part D drug on its prescription drug plan's or MA-PD plan's formulary.

(3) The provision of information in writing, upon request.

(e) *Claims information.* A PDP sponsor or MA organization offering qualified prescription drug coverage must furnish to enrollees, in a form easily understandable to such enrollees, an explanation of benefits when prescription drug benefits are provided under qualified prescription drug coverage. The explanation of benefits must—

(1) List the item or service for which payment was made and the amount of the payment for each item or service.

(2) Include a notice of the individual's right to request an itemized statement.

(3) Include the cumulative, year-to-date total amount of benefits provided, in relation to—

(i) The deductible for the current year.

(ii) The initial coverage limit for the current year.

(iii) The annual out-of-pocket threshold for the current year.

(4) Include the cumulative, year-to-date total of incurred costs to the extent practicable.

(5) Include any applicable formulary changes as described in § 423.120(b)(5).

(6) Be provided during any month when prescription drug benefits are provided under this part.

§ 423.132 Public disclosure of pharmaceutical prices for equivalent drugs.

(a) *General requirements.* Except as provided under paragraph (c) of this section, a PDP sponsor or an MA organization offering an MA-PD plan must require a pharmacy that dispenses a covered Part D drug to inform an enrollee of any differential between the price of that drug and the price of the lowest priced generic version of that drug available at that pharmacy, unless the particular covered Part D drug being purchased is the lowest-priced generic version of that drug available at that pharmacy.

(b) *Timing of notice.* Subject to paragraph (d) of this section, the information under paragraph (a) of this section must be provided at the point of sale or, in the case of dispensing by mail order, at the time of delivery of the drug.

(c) *Waiver of public disclosure requirement.* CMS waives the requirement under paragraph (a) of this section in the case of—

(1) An MA private fee-for-service plan described in § 422.4 of this chapter that—

(i) Offers qualified prescription drug coverage and provides plan enrollees

with access to covered Part D drugs dispensed at all pharmacies, without regard to whether they are contracted network pharmacies; and

(ii) Does not charge additional cost-sharing for access to covered Part D drugs dispensed at out-of-network pharmacies.

(2) An out-of-network pharmacy;

(3) An I/T/U network pharmacy; and

(4) A network pharmacy that is located in any of the U.S. territories; and

(5) Such other circumstances where CMS deems compliance with the requirements of paragraph (a) of this section to be impossible or impracticable.

(d) *Modification of timing requirement.* CMS modifies the requirement under paragraph (b) of this section as follows—

(1) For long-term care network pharmacies, which must meet the requirement in paragraph (a) of this section within a time period specified by CMS; and

(2) Under such other circumstances where CMS deems compliance with the requirement under paragraph (b) of this section to be impossible or impracticable.

§ 423.136 Privacy, confidentiality, and accuracy of enrollee records.

The provisions of § 422.118 of this chapter apply to a PDP sponsor and prescription drug plan in the same manner as they apply to an MA organization and an MA plan.

Subpart D—Cost Control and Quality Improvement Requirements for Prescription Drug Benefit Plans

§ 423.150 Scope.

The regulations in this subpart specify requirements relating to the following:

(a) Cost and utilization management programs, quality assurance programs, medication therapy management programs (MTMP), and programs to control fraud, abuse, and waste for PDP sponsors and MA organizations offering MA-PD plans.

(b) CMS consumer satisfaction surveys of prescription drug plan and MA-PD.

(c) Electronic prescription program.

(d) Compliance deemed on the basis of accreditation.

(e) Accreditation organizations.

(f) Procedures for the approval of accreditation organizations as a basis for deeming compliance.

§ 423.153 Cost and utilization management, quality assurance, medication therapy management programs, and programs to control fraud, abuse, and waste.

(a) *General rule.* Each PDP sponsor or MA organization offering an MA-PD plan must have established, for covered Part D drugs, furnished through a prescription drug plan or MA-PD plan, a cost-effective drug utilization management program, a quality assurance program, an MTMP, and a program to control fraud, abuse, and waste as described in § 423.153(b), § 423.153(c), § 423.153(d), and § 423.153(e) of this section.

(b) *Cost-effective drug utilization management.* A cost-effective drug utilization management program must—

(1) Include incentives to reduce costs when medically appropriate; and

(2) Maintain policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications.

(c) *Quality assurance program.* A quality assurance program must include measures and systems to reduce medication errors and adverse drug interactions and improve medication use. The program must establish processes for—

(1) Drug utilization review;

(2) Patient counseling; and

(3) Patient information record-keeping

(d) *Medication therapy management program.* (1) *General rule.* A medication therapy management program—

(i) Must assure that drugs prescribed to targeted beneficiaries described in paragraph (d)(2) of this section are appropriately used to optimize therapeutic outcomes through improved medication use;

(ii) Must, for the targeted beneficiaries described in paragraph (d)(2) of this section, reduce the risk of adverse events, including adverse drug interactions;

(iii) May be furnished by a pharmacist; and

(iv) May distinguish between services in ambulatory and institutional settings.

(2) *Targeted beneficiaries.* Targeted beneficiaries for the medication therapy management program described in paragraph (d)(1) of this section are enrolled Part D eligible individuals who—

(i) Have multiple chronic diseases;

(ii) Are taking multiple covered Part D drugs; and

(iii) Are likely to incur annual costs for covered Part D drugs that exceed a predetermined level that CMS determines.

(3) *Use of experts.* The MTMP must be developed in cooperation with licensed

and practicing pharmacists and physicians.

(4) *Coordination with care management plans.* The MTMP must be coordinated with any care management plan established for a targeted individual under a chronic care improvement program under section 1807 of MMA.

(5) *Considerations in pharmacy fees.* An applicant to become a PDP sponsor or an MA organization wishing to offer an MA-PD plan must—

(i) Describe in its application how it will take into account the resources used and time required to implement the MTMP it chooses to adopt in establishing fees for pharmacists or others providing medication therapy management services for covered Part D drugs under a prescription drug plan.

(ii) Disclose to CMS upon request the amount of the management and dispensing fees and the portion paid for medication therapy management services to pharmacists and others upon request. Reports of these amounts are protected under the provisions of section 1927(b)(3)(D) of the Act.

(e) *Program to control fraud, abuse, and waste.* PDP sponsors and MA organizations offering MA-PD plans must develop performance standards to evaluate, prevent, and investigate fraud, abuse, and waste. These standards will apply to the PDP sponsor's or MA organization's evaluation of PDPs, MA-PDs, pharmacy benefit managers, or other subcontractors managing or coordinating the benefit for the organization or sponsor, pharmacies, physicians, and any other providers with whom the PDP sponsor or MA organizations does business.

(f) *Exception for private fee-for-service MA plans offering qualified prescription drug coverage.* In the case of an MA plan described in § 422.4(a)(3) of this chapter, the requirements under paragraphs (b) and (d) of this section do not apply.

§ 423.156 Consumer satisfaction surveys.

CMS conducts consumer satisfaction surveys of PDP and MA-PD enrollees similar to the surveys it conducts of MA enrollees under § 422.152 (b) of this chapter.

§ 423.159 Electronic prescription program.

(a) *Electronic prescription standards.* PDP sponsors and MA organizations offering qualified prescription drug coverage must have the capacity to support and must comply with electronic prescription standards relating to covered Part D drugs, for Part D eligible individuals, developed by CMS, once final standards are effective.

(b) *Promotion of electronic prescribing by MA-PD plans.* An MA organization offering an MA-PD plan may provide for a separate or differential payment to a participating physician that prescribes covered Part D drugs in accordance with electronic prescription standards, including voluntary standards promulgated by CMS as well as final standards established by CMS once final standards are effective.

§ 423.162 Quality Improvement Organization activities.

(a) *General rule.* Quality Improvement Organizations (QIOs) are required to offer providers, practitioners, MA organizations, and PDP sponsors quality improvement assistance pertaining to health care services, including those related to prescription drug therapy. QIOs offer assistance according to contracts established with the Secretary.

(b) *Collection of information.* Information collected, acquired, or generated by a QIO in the performance of its responsibilities under this section is subject to the confidentiality provisions of 42 CFR Part 480. PDP sponsors and MA organizations offering MA-PD plans are required to provide specified information to CMS for distribution to the QIOs as well as directly to QIOs.

(c) *MA organizations and PDP sponsors.* For purposes of 42 CFR Parts 476 and 480, MA organizations and PDP sponsors are included in the definition of "health care facility."

§ 423.165 Compliance deemed on the basis of accreditation.

(a) *General rule.* A PDP sponsor or MA organization offering an MA-PD plan is deemed to meet all of the requirements of any of the areas described in paragraph (b) of this section if—

(1) The PDP sponsor or MA organization is fully accredited (and periodically reaccredited) for the standards related to the applicable area under paragraph (b) of this section by a private, national accreditation organization approved by CMS; and

(2) The accreditation organization uses the standards approved by CMS for the purposes of assessing the PDP sponsor or MA organization's compliance with Medicare requirements.

(b) *Deemable requirements.* The requirements relating to the following areas are deemable:

(1) Access to covered drugs, as provided under § 423.120 and § 423.124.

(2) Cost and utilization management, quality assurance, medication therapy management programs, and programs to