(B) *For subsequent Round bids.* CMS has 90 days after the covered document review date to provide notify suppliers of any missing covered documents.

(iii) *Submission of missing covered documents.* Suppliers notified by CMS of missing covered documents have 10 business days after the date of such notice to submit the missing documents. CMS does not reject the supplier's bid on the basis that the covered documents are late or missing if all the applicable missing covered documents identified in the notice are submitted to CMS not later than 10 business days after the date of such notice.

* * * * *

■ 7. Section 414.422 is amended by—

■ A. Redesignating paragraph (f) as paragraph (g).

■ B. Adding a new paragraph (f).

The addition reads as follows:

§ 414.422 Terms of contracts.

* * * * *

(f) *Disclosure of subcontracting arrangements.*

(1) *Initial disclosure.* Not later than 10 days after the date a supplier enters into a contract under this section the supplier must disclose information on both of the following:

(i) Each subcontracting arrangement that the supplier has in furnishing items and services under the contract.

(ii) Whether each subcontractor meets the requirement of section 1834(a)(20)(F)(i) of the Act if applicable to such subcontractor.

(2) *Subsequent disclosure.* Not later than 10 days after the date a supplier enters into a subcontracting arrangement subsequent to contract award with CMS, the supplier must disclose information on both of the following:

(i) The subcontracting arrangement that the supplier has in furnishing items and services under the contract.

(ii) Whether the subcontractor meets the requirement of section 1834(a)(20)(F)(i) of the Act, if applicable to such subcontractor.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 13, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: December 5, 2008.

Michael O. Leavitt,

Secretary.

[FR Doc. E9–863 Filed 1–15–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 423

[CMS 4138–IFC4]

RIN 0938–AP24

Medicare Program: Medicare Advantage and Prescription Drug Programs MIPPA Drug Formulary & Protected Classes Policies

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

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period revises the regulations governing the Medicare prescription drug benefit program (Part D). This regulation makes conforming changes to reflect revisions to the rules governing Part D that were made as a result of provisions in the Medicare Improvements for Patients and Providers Act (MIPPA), which became law on July 15, 2008. These MIPPA provisions change the definition of a covered Part D drug, and add new requirements that apply to Part D formularies.

DATES: *Effective date:* These regulations are effective January 16, 2009.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on March 17, 2009.

ADDRESSES: In commenting, please refer to file code CMS–4138–IFC4. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' and enter the file code to find the document accepting comments.

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4138–IFC4, P.O. Box 8016, Baltimore, MD 21244–8016.

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

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4138–IFC4, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

a. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201;

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

b. 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

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

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Alissa DeBoy at (410) 786–6041)or Vanessa Duran at (410)786–8697.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have

been received: *http://regulations.gov. Follow the search instructions* on that Web site to view public comments.

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

I. Background

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) was enacted on December 8, 2003. Section 101 of title I of the MMA added a new ''Part D'' to title XVIII of the Social Security Act (the Act), creating the Medicare prescription drug benefit program. The prescription drug benefit program is one of the most significant changes to the Medicare program since its inception in 1965. The MMA also made revisions to the provisions in Medicare Part C, governing what is now called the Medicare Advantage (MA) program (formerly Medicare+Choice). The MMA directed that important aspects of the new Medicare prescription drug benefit program under Part D be similar to and coordinated with regulations for the MA program.

A final rule implementing the Part D prescription drug program appeared in the **Federal Register** on January 28, 2005 (70 FR 4194). The provisions of that rule became effective on March 22, 2005.

The Medicare Improvements for Patients and Providers Act (MIPPA) (Pub. L. 110–275) was enacted on July 15, 2008. MIPPA made a number of changes to the statutory provisions governing both the MA program under Part C and the prescription drug program under Part D. On September 18, 2008, we published an interim final rule with comment period that made a wide array of revisions to regulations governing the Part C and Part D programs to reflect changes in the statutory provisions governing these programs made in MIPPA [see 73 FR 54226]. This interim final rule with comment period similarly makes conforming changes to the Part D regulations to reflect certain statutory changes made in MIPPA that were not addressed in the September 18, 2008 interim final rule.

II. Provisions of the Interim Final Rule

A. Medically Accepted Indication (§ 423.100 Definitions)

Section 182 of MIPPA amends section 1860D–2(e)(1) of the Act to add a new definition for ''medically accepted indication,'' effective January 1, 2009, for Part D drugs used in anticancer chemotherapeutic regimens, specifically, and all other Part D drugs. Under new section 1860D–2(e)(4) of the Act, a ''medically accepted indication'' for Part D drugs used in anticancer chemotherapeutic regimens has the meaning given in section 1861(t)(2)(B) of the Act, except that in applying the 1861(t)(2)(B) definition, the terms ''prescription drug plan'' or ''MA–PD plan'' are substituted for ''carrier,'' and the compendia described in section 1927(g)(1)(B)(i)(III) of the Act are added to those listed in section 1861(t)(2)(B)(ii)(I) of the Act. Also, on and after January 1, 2010, this last requirement shall not apply unless the compendia described in section 1927(g)(1)(B)(i)(III) of the Act meets the requirement in the third sentence of section 1861(t)(2)(B) of the Act.

Also under section 182 of MIPPA, for all Part D drugs not used in anticancer chemotherapeutic regimens, ''medically accepted indication'' has the meaning given in section 1927(k)(6) of the Act, except that in applying this provision, the Secretary shall revise the list of compendia described in section 1927(g)(1)(B)(i) of the Act as appropriate for identifying medically accepted indications for drugs, in a manner consistent with the process for revising compendia under section 1861(t)(2)(B) of the Act.

Consistent with these new statutory requirements, we have amended § 423.100 by revising the definition of a Part D drug at § 423.100 to incorporate the new definition of medically accepted indication in section 1860D–2(e)(4) of the Act.

B. Access to Covered Part D Drugs (§ 423.120)

Section 176 of MIPPA added a new section 1860D–4(b)(3)(G)(i) to the Act requiring, effective for plan year 2010, that CMS identify, as appropriate, certain categories or classes of drugs which meet the following two pronged test: (1) Restricted access to the drugs in the category or class would have major or life threatening clinical consequences for individuals who have a disease or disorder treated by drugs in such category or class; and (2) there is a significant need for such individuals to have access to multiple drugs within a category or class due to unique chemical actions and pharmacological effects of the drugs within the category or class, such as drugs used in the treatment of cancer.

Under a new section 1860D–4(b)(3)(G)(ii) of the Act, subject to the authority in section 1860D–4(b)(3)(G)(iii) of the Act to provide for exceptions, Part D formularies must include all covered Part D drugs in each class identified under section 1860D–4(b)(3)(G)(i) of the Act. Section 1860D–4(b)(3)(G)(iii), in turn, provides CMS the discretion to establish exceptions permitting sponsors of a prescription drug plan to exclude from their formularies, or to otherwise limit access to (including through prior authorization or other utilization management restrictions), certain Part D drugs from the protected categories and classes established consistent with section 1860D–4(b)(3)(G)(i) of the Act. As provided in section 1860D–4(b)(3)(G)(iii)(I) of the Act, any such exception must be based on scientific evidence and medical standards of practice (and, in the case of antitretroviral medications, be consistent with the Department of Health and Human Services Guidelines for the Use of Antitretroviral Agents in HIV–1–Infected Adults and Adolescents). In addition, as provided in section 1860D–4(b)(3)(G)(iii)(II) of the Act, such exceptions must be provided under a process that includes an opportunity for public notice and comment. We have added § 423.120(b)(2)(v) to reflect the new formulary requirements in section 1860D–4(b)(3)(G) of the Act.

Based on our program experience, and consistent with our formulary review process, we plan to conduct an examination, described below, of widely used treatment guidelines in order to establish protected categories and classes for Part D sponsors that meet the requirements established by section 1860D–4(b)(3)(G) of the Act. Additionally, consistent with section 1860D–4(b)(3)(G)(iii) of the Act and § 423.120(b)(2)(v) of this interim final rule, we may establish exceptions to the requirement that Part D sponsors include all Part D drugs in the protected categories and classes. Given the complexity involved in modern medicine and changes in drug therapies with availability of new information reaching providers almost daily, we anticipate that exceptions to our regulatory requirements will be necessary. For example, we believe that in certain circumstances the application of prior authorization may be appropriate to ensure use of Part D drugs in line with medically necessary

indications. As described below, we will therefore establish exceptions to the protected categories and classes through notice-and-comment rulemaking to ensure that they are established in a manner that provides for meaningful public input, in a fully transparent manner (in which we will formally respond to the public comments), that also enables us to meet operational timeframes.

We note that Part D sponsors may apply edits to make appropriate coverage determinations for drugs included in the protected classes that may be covered under Medicare Part B. Until the Part D sponsor is able to affirm there is no Part B reimbursement, we do not consider the definition of a Part D drug to be satisfied. Furthermore, the limitation of drug utilization management relating to drugs in the protected classes does not extend to the application of safety edits. Part D sponsors and their subcontracted network pharmacies must apply established safety edits to drugs from the protected classes to ensure their enrollees are not harmed by inadvertent medication errors.

We also note that, as stated in our January 28, 2005 Part D final rule (70 FR 4194, 4260), inclusion of ''all covered Part D drugs'' from a protected class or category does not extend to inclusion of all brand-name drugs and generic versions of the covered drug in question. Under our longstanding interpretation of the term ''covered Part D drug,'' Part D sponsors will only be required to include on their formularies all chemically distinct drugs from the protected classes or categories in order to the meet the provisions of § 423.120(b)(2)(v). We have consistently held that two drug products that are determined to be therapeutic equivalents by the Food and Drug Administration (FDA) and identified as such in the FDA's Orange Book are considered to be the same Part D ''drug.'' (According to the Orange Book: ''Drug products are considered to be therapeutic equivalents only if they are pharmaceutical equivalents and if they can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.'') Thus, therapeutic equivalents are not counted twice for purposes of satisfying the CMS minimum formulary requirements.

In planning for the implementation of section 1860D–4(b)(3)(G) of the Act, we note that we have gained valuable experience since 2006 in evaluating various drug classification systems and ensuring that Medicare beneficiaries reliant on drugs contained in certain categories or classes are neither substantially discouraged from enrolling in a Part D plan nor experience unnecessary complications related to accessing these drugs. Our experience has provided insight into the type of evaluation process that will be required to ensure that the classes and categories of drugs we are protecting are appropriate. In this rule, below, we describe our current thinking on the process we believe will allow us to most appropriately identify the classes and categories of drugs that should be protected. We would welcome comments on this process.

We believe that it is necessary to establish a multi-level review process to ensure that we are appropriately identifying classes or categories that meet the criteria set forth in section 1860D–4(b)(3)(G)(i) of the Act. Under this multi-level process, we are planning on conducting an initial analysis that is predominantly research and data driven, followed by a secondary clinical analysis that will serve as a validation review. Both processes will involve the identification of potential exceptions to the protected categories or classes provision.

We plan on initiating the first-level review by selecting a contractor familiar with our CMS Part D formulary process. This contractor will review all the widely used treatment guidelines and generate a list highlighting those categories or classes in which multiple drugs within classes or categories are typically used to treat a specific disorder. Simultaneously, CMS will provide information to the contractor on beneficiary utilization of multiple drugs within categories and classes based on analysis of prescription drug event (PDE) data. The contractor will relate these findings to the information obtained from the examination of widely used treatment guidelines.

For the second level validation, an expert panel of physicians and pharmacists will be organized to review the initial data developed from the contractor and offer recommendations based on a consensus opinion on the identification of protected categories and classes under the statute. Information regarding the independence, potential conflicts of interest, expertise, and balance of the individuals chosen to participate in this expert panel will be made publicly available.

We firmly believe an expert panel can assist us in appropriately weighing the data derived from the initial analysis against the statutory requirements to identify protected categories or classes of drugs in which ''access to multiple drugs within a category or class'' is needed and in which ''major or life threatening clinical consequences'' may arise if access is restricted. Furthermore, we believe the expert panel will be well positioned to consider the data suggesting possible exceptions and overlay this with the protected categories or classes in order to identify exceptions that are based upon available scientific evidence and medical standards of practice. These exceptions will be subject to notice and comment as previously described.

The results from the panel on the protected classes and exceptions will then be published in the **Federal Register** in a notice of proposed rulemaking seeking public comment, to be followed by the issuance of a final rule that responds to the public's comments. We believe that reliance on the rulemaking process will better facilitate openness and transparency of the process for identifying, as appropriate, classes and categories of drugs that meet the MIPPA criteria.

Given the contracting activities and subsequent extensive analysis necessary for reviewing all widely used treatment guidelines relative to the requirements of section 1860D–4(b)(3)(G)(i) of the Act, as well as commonly-used drug classification systems, we have determined that we will be unable to complete a full evaluation of what constitutes a protected category or class under the criteria set forth in section 1860D–4(b)(3)(G)(i) of the Act in time for the 2010 plan year, as this would require that we hire a contractor, convene an expert panel, and go through notice of proposed and final rulemaking prior to April 2009, when Part D sponsors are required to submit their formularies. Therefore, although the new regulation text at 42 CFR 423.120(b)(2)(v) states that ''Effective contract year 2010,'' formularies must include all Part D drugs in the categories or classes CMS has identified as meeting the MIPPA criteria, in practice, CMS will not have identified any such categories or classes for the contract year 2010.

Rather, for 2010, given the timeframes discussed above, as well as the need to ensure consistency in formulary coverage as we complete our analysis to implement the requirements of section 1860D–4(b)(3)(G)(i) of the Act, in the meantime we will retain our existing six classes of clinical concern contained in Chapter 6 of the Medicare Prescription Drug Benefit Manual (section 30.2.5), which were incorporated into the Manual under the statutory authority set out in section 1860D–11(e)(2)(D)(i) of

the Act. Accordingly, Part D sponsors will continue to be expected to include all or substantially all drugs in the antidepressant, antipsychotic, and anticonvulsant classes, immunosuppressant (for prophylaxis of organ transplant rejection), antiretroviral, and antineoplastic (those not generally covered under Part B) drugs for coverage year 2010. We are retaining the policy providing for coverage of all or substantially all drugs in these six classes under our existing authority in section 1860D–11(e)(2)(D)(i) of the Act in order to ensure that Part D sponsors do not discriminate against any class of beneficiary by substantially discouraging enrollment.

For contract years 2011 and beyond, any modifications we make to the protected categories and classes, whether under the existing MMA non-discrimination authority or new authority under MIPPA, will be made through notice-and-comment rulemaking. Specifically, prior to establishing the protected categories and classes under the new MIPPA authority, CMS will (i) engage in an identification and validation process, such as the process described above and (ii) engage in a process of notice and comment rulemaking for any modifications (including any additions, subtractions, or exceptions) to the protected categories and classes under the MIPPA authority. In such rulemaking, or a separate rulemaking, we may further articulate our interpretation of the new statutory criteria. We believe that asking for (and responding to) public comment on results from the contractor and expert panel will better facilitate openness and transparency of the process for identifying, as appropriate, classes and categories of drugs that meet the MIPPA criteria.

Similarly, if CMS makes modifications to the existing protected categories and classes under the MMA authority (i.e., the existing six classes of clinical concern), we will (i) engage in an identification and validation process, such as the process described above and (ii) engage in notice and comment rulemaking for any such modifications (including any additions, subtractions, or exceptions). Any such rulemaking may also further articulate our interpretation of the statutory language at section 1860D–11(e)(2)(D)(i) of the Act. This process will mirror the process for establishing the protected categories and classes under the new MIPPA authority. Soliciting, and responding to, public comment on results from the contractor and expert panel will increase the openness and transparency of the process for protecting classes and categories of drugs under the MMA non-discrimination authority.

In the past, we have used annual Call Letters and other guidance memorandums to announce the policy of expecting plan sponsors to cover ''all or substantially all'' drugs in the six classes of clinical concern. We announced the policy to ensure that enrollees had as smooth of a transition as possible into the Part D program. We also wanted to minimize potential beneficiary concern about access to drugs in the six protected classes and categories.

However, we now have much more experience with Part D since the program started in January 2006. Thus, we are in a better position to consider drug categories and classes that should receive protection either under MIPPA or the MMA. Further, the public now has greater experience with a fully implemented Part D program and can provide more comprehensive comments on our continuing considerations about the program.

Hence, CMS has decided that any modifications to the current six categories and classes, whether under MIPPA or the MMA authority, will go through the process described above that includes notice of proposed and final rulemaking. The rulemaking process will provide for more transparency in the process of identifying protected categories and classes, enabling the public to comment on how modifications to the current six classes will impact various stakeholders, including beneficiaries, beneficiary advocates, plan sponsors, contractors of plan sponsors, and governmental entities, among others.

In addition, CMS believes that identifying protected classes and categories in the Code of Federal Regulations will provide greater clarity and transparency about those drug classes that are protected.

III. Waiver of Proposed Rulemaking and Delay in Effective Date

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived; however, if an agency finds good cause that a notice and comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued. We also usually provide for a delay in effective date under section 553(d) of the APA (5 U.S.C. 553(d), as well as section 801(a)(3) of the Congressional Review Act (5 U.S.C. 801(a)(3)) (when applicable). However, such delay in effective date may be waived for good cause, when such delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the finding and a brief statement of the reasons therefore in the notice. 5 U.S.C. 553(d)(3), 808(2). Because this interim final rule simply makes conforming changes to the Code of Federal Regulations to reflect changes in the statute, we find it would be unnecessary and contrary to the public interest to seek public comment on these provisions. For the same reasons, we also find that it would be unnecessary and contrary to the public interest to delay the effective date of such provisions beyond January 16, 2009.

IV. Collection of Information Requirements

This document does not impose any new information collection and recordkeeping requirements. Currently approved and forthcoming controls account for any collection of information burden relative to the provisions of this interim final rule, as outlined below.

Section 423.120 Formulary Requirements

Section 423.120(b)(2)(v) requires Part D sponsors to include in their contract year 2010 formularies all drugs in certain protected categories of classes of drugs specified by CMS, with certain exceptions that CMS establishes.

The burden associated with this requirement is the time and effort put forth by Part D sponsors to submit their formularies to CMS. These collection of information requirements are currently approved under the Office of Management and Budget (OMB) Control No. 0938–0763.

V. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993, as further amended), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the

Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866, as amended, directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate that this interim final rule with comment is economically significant under the Executive Order 12866, as it contains impacts of $100 million or more in any one year, and hence also a major rule under the Congressional Review Act.

The RFA requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and supplies are small entities, either by nonprofit status or by having revenues of $7 million or less to $34.5 million in any 1 year. Individuals and States are not included in the definition of a small entity.

We estimate that the coverage of all drugs by Part D sponsors from the CMS-established protected classes or categories to have a cost impact to the federal budget in an amount exceeding $100 million for any given calendar year (CY). Table 1 provides the costs associated with these provisions for CY 2010 through CY 2018. The assumptions underlying these cost estimates are explained later in this section.

With respect to economic benefits, we have no reliable basis for estimating the effects of the proposals contained in this IFC. Accordingly, we estimate that while there could be economic benefits associated with these proposals, they are difficult to gauge at this time.

The economically significant costs are reflected below in table 1.

TABLE 1—PROJECTED PART D COSTS FOR CY 2010—CY 2018

[Amounts in $ millions]

	CY 2010	CY 2011	CY 2012	CY 2013	CY 2014	CY 2015	CY 2016	CY 2017	CY 2018	CY 2010–2018
Formulary requirements with respect to certain categories or classes of drugs	0	160	340	460	520	570	640	710	800	4200

We note that the change in the definition of a Part D drug to revise the meaning of the term ''medically accepted indication,'' as provided under section 1860D–2(e)(4) of the Act, was scored at zero additional cost to the program. Most of the anticancer chemotherapeutic regimens utilized by Medicare beneficiaries are covered under Part B, and while this new provision may extend coverage for anticancer therapeutic regimens under Part D, we believe the number of Part D drugs claims impacted by this change will be minimal. Therefore, we do not expect that this provision will significantly impact program costs.

a. Regulatory Flexibility Analysis

Under the RFA, we are not required to conduct an initial regulatory flexibility analysis for interim final rules. However, it is our longstanding policy to provide an analysis whenever we believe it would aid in the understanding of the effects of the interim final rule with comment.

The RFA requires agencies to determine whether a rule will have a ''significant economic impact on a substantial number of small entities.'' Under the RFA, a ''small entity'' is defined as a small business (as determined by the Small Business Administration (SBA)), a non-profit entity of any size that is not dominant in its field, or a small government jurisdiction. HHS uses its measure of a significant economic impact on a substantial number of small entities to be a change in revenues of more than 3 to 5 percent.

With respect to the provisions contained in this interim final rule, we believe only retail pharmacies which are small businesses will be impacted. Other small businesses, such as physicians in private practice or small businesses that deliver prescriptions to beneficiaries, will be unaffected by this interim final rule since there is no direct impact to their operations or profitability. For example, private physicians will generally continue to follow current prescribing practices regardless of Part D formularies. Small delivery businesses will continue to deliver the same number of prescriptions regardless of the drug name or formulary inclusion.

The Small Business Administration (SBA) considers pharmacies with firm revenues less than $7 million to be small businesses. The 2004 Business Census (the latest available detailed data) indicated that there were approximately 19,443 firms operating about 40,115 retail pharmacies and drug store establishments (NAICS code 44611). Of these firms, 17,835 had revenues under $7 million and operated a total of 17,835 establishments. As a result, we estimate that more than 90 percent of retail pharmacy firms are small businesses (as defined by the SBA size standards).

We do not believe that retail pharmacies would be significantly impacted by the requirement for Part D sponsors to include all drugs in protected classes or categories specified by CMS. While the number of brand name drugs dispensed in these categories may increase, we do not think there will be a substantial increase in overall retail pharmacy profits. Retail pharmacies may incur some limited costs relative to this provision, since they may need to inventory more drugs within these classes given that Part D sponsors may not be able to concentrate volume on lower cost salts, esters and active moieties.

As previously discussed, the other change contained in this interim final rule is not expected to affect small businesses in a significant manner, if at all. For example, section 182 of the MIPPA requires modification to the definition of a medically accepted indication for purposes of a Part D drug. While Part D sponsors will be expected to implement this new definition through their drug utilization management programs, small

businesses, such as retail pharmacies or physicians, will not require any changes to their existing operations. The application of drug utilization management is common in the commercial market, and small businesses already have processes (that is, administrative staff or pharmacy technicians) to supply the necessary information to address drug utilization management requirements. As a result, we do not anticipate any additional costs or burdens to be placed on other small businesses.

Section 1102(b) of the Social Security Act requires us to prepare a regulatory flexibility impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. This interim final rule will not affect small rural hospitals since the program will be directed at outpatient prescription drugs, not drugs provided during a hospital stay. As required by law, prescription drugs provided during hospital stays are covered under a separate Medicare payment system. Therefore, we are not providing an analysis in this rule.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million. That threshold, updated for inflation, is currently approximately $130 million. We anticipate that this interim final rule will not impose costs above the $130 million UMRA threshold on State, local, tribal governments, in the aggregate, or by the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. The changes and additions contained in this interim final rule do not impose new costs on states or local governments.

There are no anticipated Federalism implications because none of the provisions contained in this interim final rule place any requirements on States.

B. Anticipated Effects on Health Plans and Pharmacy Benefit Managers (PBMs)

Part D sponsors will be significantly impacted by this IFC rule. For example, we believe that the new provision relative to the establishment of certain protected classes and categories of Part D drugs will have a significant impact on Part D sponsors, a class of beneficiaries and the Federal Government. This new provision requires that Part D sponsors include all drugs in protected classes and categories of drugs that CMS specifies as meeting both of the following conditions:

1. Restricted access to drugs in the category or class would have a major or life threatening clinical consequence.

2. A significant clinical need exists for individuals to have access to multiple drugs within a category or class due to unique chemical actions and pharmacological effects.

We expect these conditions will likely expand access to drugs for certain classes or categories and provide greater inclusion of manufacturers' drugs associated with those classes or categories in the Part D program. If additional drug classes and categories are required to be included on Part D sponsor formularies, Part D sponsors' costs could increase, since more drugs could need to be covered. Conversely, if fewer classes and categories are required to be included on Part D sponsors' formularies, Part D sponsors' costs could decrease, since less drugs could require coverage. Since we are only now beginning our examination of widely used treatment guidelines in order to establish the protected classes or categories that meet the aforementioned requirements, we estimate that this provision will add an additional $160 million to the cost of the Part D program in CY 2011. We believe this will increase to $800 million in CY 2018, with total costs of approximately $4.2 billion dollars for the period CY 2010 through CY 2018.

To arrive at the cost estimate for the implementation of the protected categories and classes, we began by putting drug spending into 3 groupings: (1) Drugs that were already included in the six classes of clinical concern; (2) drugs with a greater likelihood of being affected by this statutory change; and (3) drugs with a lesser likelihood of being affected by this statutory change. For each of these categories, we estimated the likelihood that they would ultimately be included in the protected categories and classes. A very preliminary review of commonly used classification systems revealed that additional categories and classes of drugs may be included in the protected categories and classes based upon the statutory requirements in section 1860D–4(b)(3)(G)(i) of the Act. We assumed that it would take several years for the full impact of this policy to take effect as new formulary requirements are fully implemented and manufacturers discover their new negotiating positions. Finally, we estimated the impact on drug expenditures for those drugs that could potentially be moved into protected categories or classes of drugs based on the statutory requirements. These impacts reflect our best estimates of a range of possibilities that cannot be more accurately projected until actual decisions are made.

There is a large amount of uncertainty in the cost impact presented above. As described above, the cost impact is calculated based on making a series of assumptions regarding potential classes that may become protected. It is possible that the actual number of classes that would be protected will be different than we've estimated. For example, if no classes beyond the current six become protected, there would be no cost impact at all. Alternatively, if a greater number of classes than we estimate become protected, the actual cost impact will be greater than presented above. Moreover, if this process only resulted in the elimination of the existing six classes, savings could accrue.

If additional categories and classes are included on Part D sponsor formularies as a result of the new statutory provisions, we expect sponsors' negotiating power to be diminished. If this were to occur, Part D sponsors could incur higher drug costs and could be forced to raise their bids, which could result in higher premiums and co-pays to offset these increases. We also anticipate that Part D sponsors could have additional costs associated with managing a larger overall formulary—for example, increased Pharmacy and Therapeutics Committee oversight and increased expenses in marketing more products on comprehensive formularies. Alternatively, however, the number of protected classes and categories meeting the MIPPA requirement could decline relative to the current six protected under the MMA authority. If this were the case, we expect Part D sponsors' negotiating power to increase. As a result, Part D sponsors could incur lower drug costs and could lower their bids, which could result in lower premiums and co-pays.

We are also uncertain at this time what exceptions to the requirement that Part D sponsor formularies include all

drugs in the protected categories and classes of drugs will be established by CMS. We anticipate establishing exceptions similar to those available under our existing six classes of clinical concern policy. It is possible we will establish fewer exceptions, and Part D sponsors may have to include more drugs on their formularies than current policy. However, it is also possible that we may establish more exceptions than current policy. We are also uncertain how Part D sponsors will be permitted to apply drug utilization management to drugs in the protected classes until we finalize the exceptions to the protected categories and classes requirement. We believe that if we are unable to permit Part D sponsors to apply meaningful utilization management to these drugs—even if only for beneficiaries initiating therapy in these categories or classes—the result could be an increased use of brand-name or higher cost drugs and an increase in costs overall. These costs could be reflected in bids submitted to CMS by Part D sponsors and could result in increased premiums for Medicare beneficiaries. We plan on working closely with all of our Part D sponsors as our guidance in this area develops to ensure they have the information they need to negotiate as efficiently as possible and continue to provide high quality prescription drug coverage at the most economical price.

Except for the potential impact of increased or decreased costs (that is, increased or decreased copayments and premiums) on beneficiaries, we do not believe that the implementation of the protected classes and categories requirement will negatively impact enrollment in Part D plans. We also do not believe that the provisions of this rule will lead to greater beneficiary confusion or any increased difficulty in making enrollment decisions. While increased copayments and premiums may dissuade some beneficiaries from enrolling in particular Part D plans, we continue to believe that overall enrollment will increase given demographic trends and the increasing cash prices for drugs. Accordingly, we believe Medicare beneficiaries will continue to find Part D to be a cost efficient method of obtaining robust drug coverage at a range of acceptable costs.

We also believe that PBMs could experience higher administrative costs as a result of the provisions contained in this rule. The protected classes provision may increase a number of formulary maintenance expenses ranging from managing a larger formulary to increased support of technical call centers to address requests for assistance in processing a wider range of covered drugs. As a result, PBMs may increase their fees to Part D sponsors to offset these increased costs. We do not believe these additional costs will negatively impact the PBM industry given its ability to pass these onto the Part D sponsors. Similar to our ongoing communications with our Part D sponsors, we intend to work closely with the PBM industry to ensure as much efficiency as possible and minimize any resulting increases in beneficiary costs.

C. Alternatives Considered

All of the provisions in this interim final rule are a result of the recent passage of the MIPPA and are largely self-implementing. With the publication of this interim final rule, we desire to make our implementing regulations available to industry and the public as soon as possible to facilitate continued, efficient operation of the Parts C and D programs.

D. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/index.html*), Table 2 below provides an accounting statement showing the classification of the expenditures associated with the provisions of this IFC rule. This table provides our best estimate of the increase in costs as a result of the changes presented in this final rule. All costs, including increases and reductions, are classified as transfers by the Federal Government to Part D plans or MAOs.

TABLE 2—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

Category	Transfers ($ millions)
Formulary requirements with respect to certain categories or classes of drugs, CYs 2010–2018:	
Undiscounted Annualized Monetized Transfers	466.7.
Annualized Monetized Transfers Using 7% Discount Rate	424.5.
Annualized Monetized Transfers Using 3% Discount Rate	448.3.
From Whom to Whom?	Federal Government to Part D Plans.

D. Conclusion

Given that we expect the cost of implementing a number of the provisions contained in this IFC rule, as specified in Table 1, will exceed the $100 million threshold within a single year between CY 2010 and CY 2018, we conducted an economic impact analysis with regard to those entities potentially impacted by these provisions. As we stated previously in this preamble, we expect that entities such as pharmacies will benefit from these changes, whereas other entities, such as Part D sponsors, will experience additional costs which they will pass on to CMS through direct subsidy payments and to beneficiaries through additional premiums as reflected in their bids. In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping.

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

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

Subpart C—Benefits and Beneficiary Protections

■ 1. The authority citation for part 423 continues to read as follows:

Authority: Secs. 1102, 1106, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh).

■ 2. Amend § 423.100 by revising the introductory text of paragraph (1) under the definition of ''Part D drug'' to read as follows:

§ 423.100 Definitions.

* * * * *

Part D drug means—

(1) Unless excluded under paragraph (2) of this definition, any of the following if used for a medically accepted indication (as defined in section 1860D–2(e)(4) of the Act)—

* * * * *

■ 3. Amend § 423.120 by—

■ A. Revising (b)(2) introductory text.

■ B. Revising (b)(2)(i).

■ C. Adding (b)(2)(v).

The revisions and additions to read as follows:

§ 423.120 Access to covered Part D drugs.

* * * * *

(b) * * *

(2) Provision of an Adequate Formulary. A Part D plan's formulary must—

(i) Except as provided in paragraphs (b)(2)(ii) and (v) of this section, include within each therapeutic category and class of Part D drugs at least two Part D drugs that are not therapeutically equivalent and bioequivalent, with different strengths and dosage forms available for each of those drugs, except that only one Part D drug must be included in a particular category or class of covered Part D drugs if the category or class includes only one Part D drug.

* * * * *

(v) Effective contract year 2010, a Part D Sponsor's formulary will include all Part D drugs in a category or class that CMS has identified as meeting the two conditions set forth in section 1860D–4(b)(3)(G)(i) of the Act. CMS may establish certain exceptions, which may include the application of drug utilization management under certain circumstances, through a process that provides for public notice and comment, and ensures that any exception to such requirements is based upon scientific evidence and medical standards of practice (and, in the case of antiretroviral medications, is consistent with the Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV–1–Infected Adults and Adolescents).

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 12, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: January 9, 2009.

Michael O. Leavitt,

Secretary.

[FR Doc. E9–783 Filed 1–15–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 88 and 89

RIN 0991–AB46

Office of Global Health Affairs: Regulation on the Organizational Integrity of Entities That Are Implementing Programs and Activities Under the Leadership Act; Correction

OFFICE: Office of Global Health Affairs, HHS.

ACTION: Rule; Correction.

SUMMARY: This document corrects technical errors that appeared in the final rule published in the **Federal Register** on December 24, 2008, entitled ''Regulation on the Organizational Integrity of Entities That Are Implementing Programs and Activities Under the Leadership Act'' (73 FR 78997).

DATES: Effective January 20, 2009.

FOR FURTHER INFORMATION CONTACT: Jeanne Monahan, Office of Global Health Affairs, Hubert H. Humphrey Building, Room 639H, 200 Independence Avenue, SW., Washington, DC 20201, Tel: 202–690–6174, e-mail: *Jeanne.monahan@hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. E8–30686, published on December 24, 2008 (73 FR 78997), there were technical errors that are identified and corrected in the Correction of Errors section below. The correction of errors identified in this correction notice do not change any policies contained in the final rule published December 24, 2008, and thus are effective as if they had been included in the final rule.

II. Summary of Errors

HHS published a final rule entitled ''Regulation on the Organizational Integrity of Entities That Are Implementing Programs and Activities Under the Leadership Act.'' This final rule provided for creation of a new Part 88 of 45 CFR. A final rule published on December 19, 2008 (73 FR 78071), entitled ''Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law,'' however, also purported to create a new Part 88. We are correcting this error by creating a new Part 89 and moving the regulatory text from the final rule published on December 24, 2008 (73 FR 78997) to Part 89. We are correcting text throughout the preamble and regulatory text to reflect this move.

III. Correction of Errors

In FR Doc. E8–30686, published on December 24, 2008 (73 FR 78997), make the following corrections:

[Corrections to the preamble]

1. On page 78997, in the heading, third line, ''45 CFR Part 88'' is corrected to read ''45 CFR Part 89.''

2. On page 78998, in the first column, following the sixth full paragraph, the heading ''Section 88.1 Definitions'' is corrected to ''Section 89.1 Definitions.''

3. On page 78998, in the second column, following the fifth paragraph, the heading ''Section 88.2 Objective Integrity of Recipients'' is corrected to ''Section 89.2 Objective Integrity of Recipients.''

4. On page 78998, in the third column, in the first full paragraph, line 6, ''section 88.3'' is corrected to ''section 89.3.''

5. On page 78998, in the third column, following the first full paragraph, the heading ''Section 88.3 Certifications'' is corrected to ''Section 89.3 Certifications.''

6. On page 78998, in the third column, third full paragraph, line 3, ''section 88.3(d)(1)'' is corrected to ''section 89.3(d)(1).''

7. On page 78998, in the third column, fourth full paragraph, lines 3–4, ''section 88.3(d)(2) and (3)'' is corrected to ''section 89.3(d)(2) and (3).''

8. On page 79001, in the first column, following the second full paragraph, the heading ''List of Subjects in the 45 CFR Part 88'' is corrected to ''List of Subjects in the 45 CFR Part 89.''

[Corrections to the regulatory text]

9. On page 79001, in the first column, in the words of issuance, immediately following paragraph captioned ''Editorial Note,'' revise the paragraph to read ''For the reasons stated in the preamble, the Office of Global Health Affairs amends 45 CFR subtitle A to add Part 89 as follows:''

10. On page 79001, in the first column, in the part heading, ''Part 88'' is corrected to ''Part 89.''

11. On page 79001, in the first column, in the table of contents, ''88.1 Definitions'' is corrected to ''89.1 Definitions.''