Supporting Statement Related to Changes to Close the Part D Coverage Gap, Improvements to MTM Programs, and Independence of LTC Consultant Pharmacists

A. Background

The Centers for Medicare and Medicaid Services is proposing revisions to the Medicare Prescription Drug Benefit Program (Part D) to implement provisions specified in the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (collectively referred to as the Affordable Care Act) (ACA) and make other changes to the regulations based on our continued experience in the administration of the Part D program. These latter proposed revisions would make changes to strengthen beneficiary protections. We also are proposing an amendment to the long-term care facility conditions of participation pertaining to pharmacy services.

B. Justification

1 . Need and Legal Basis

MDBG—423.104(d)(4)

Paragraphs (b)(3) and (d) of section 1101of HCERA amended section 1860D-2(b) of the Act by adding provisions that revise the Part D benefit structure to close the gap in coverage that occurs between the initial coverage limit for the year and the out-of-pocket threshold. The new provisions not only revise the amount of coinsurance for costs of covered drugs above the initial coverage limit and below the out-of-pocket threshold (that is, within the Part D coverage gap), but also reduce the growth in the annual out-of-pocket threshold from 2014 to 2019.

Under the new provisions in section 1860D-2(b)(2)(C) and (D) of the Act, effective January 1, 2011, cost sharing in the coverage gap will be determined on the basis of whether the covered Part D drug is considered an "applicable drug" under the Medicare coverage gap discount program as defined at section 1860D-14A(g)(2). Under standard prescription drug coverage, coinsurance in the coverage gap for drugs that are not applicable drugs under the Medicare coverage gap discount program (that is, generic drugs) will be either: (1) equal to the statutory generic gap coinsurance percentage for the year; or (2) actuarially equivalent to an average expected coinsurance for covered Part D drugs that are not applicable drugs under the Medicare coverage gap discount program at the statutory generic gap coinsurance percentage for the year, as determined through processes and methods established under section 1860D-11(c) of the Act and implemented at §423.265(c) and (d) of our regulations. For applicable drugs under the Medicare gap coverage discount program, coinsurance in the coverage gap for the actual cost of the drug as defined at 423.100 minus any applicable dispensing fees will be either: 1) equal to the difference between

the applicable gap percentage for the year and the discount percentage determined under the Medicare coverage gap discount program at section 1860D-14A(4)(A) of the Act; or (2) actuarially equivalent to an average expected payment of the coinsurance for applicable covered Part D drugs at the applicable gap percentage for the year, as determined through processes and methods established under section 1860D-11(c) of the Act and implemented at §423.265(c) and (d) of our regulations.

MDBG—423.153(d)(5)

In CMS-4144-P, our proposed revision to §483.60(c)(1) would require the monthly reviews of LTC facility residents' drug regimens to be performed by a licensed pharmacist who is not employed by, and is independent of (as defined at proposed §483.60(f)), the pharmacy located in or under contract with the facility. Our proposed definition at §483.60(f) would require that the licensed pharmacist does not have a relationship with the facility's pharmacy, a pharmaceutical manufacturer or distributor, or any affiliate of these entities.

MDBG—483.60(f)

In CMS-4144-P, we are proposing a revision to the MTMP requirements related specifically to MTM services furnished in LTC facilities. Under sections 1819(b)(4) and 1919(b)(4) of the Act, LTC facilities must provide, either directly or under arrangements with others, for the provision of pharmaceutical services to meet the needs of each resident. This requirement is codified in regulations at §483.60 which require LTC facilities to employ or obtain the services of a licensed pharmacist to provide consultation on all aspects of the provision of pharmacy services in the facility, including a drug regimen review at least once a month for each facility resident. In section B of this proposed rule, we propose to amend §483.60 to include the requirement that LTC facilities employ or directly or indirectly contract the services of a licensed pharmacist who is independent.

2. Information Users

MDBG—423.104(d)(4)

Proposed §423.104(d)(4) would require the approximately 40 pharmacy claims processors currently responsible for adjudication of pharmacy benefits to identify the applicable Part D covered drugs in their systems and apply a different cost-sharing percentage when processed in the coverage gap than the percentage applied to non-applicable drugs. We estimate a one-time burden to be 12,000 hours per processor to make the initial coding changes necessary to implement this requirement and an annual burden of 250 hours per processor to perform periodic updates of the applicable drugs in their systems.

MDBG—423.153(d)(5)

We expect a total of 240 Part D parent organizations and sponsors would have a contract with an average of 802 LTC facilities.

MDBG—483.60(f)

All 15,713 LTC facilities would need to negotiate, draft, and execute contracts with

consultant pharmacists. For purposes of determining the fiscal year burden, we will assume that LTC facilities would have a contract with one consultant pharmacist.

3. Use of Information Technology

Where feasible the collection of information covered by this regulation will involve the use of automated, electronic, mechanical, or other technological collection techniques designed to reduce burden and enhance accuracy.

4. Duplication of Efforts

This is a new regulatory requirement that is not duplicative of any existing requirement.

5. Small Businesses

Some Part D organizations and LTC facilities are small businesses so they may be affected. They will have to comply with all the information requirements described in this supporting statement.

6. Less Frequent Collection

This information is collected as needed. If it were to be collected less frequently, CMS would not be able to obtain this data. Some of the consequences would be improper or erroneous payment to Part D plans, improper enrollment of beneficiaries in an organization, the release of misleading information regarding health care coverage through a plan to potential members, and inadequate provision of patients' rights to Medicare-covered services.

7. Special Circumstances

There are no special circumstances associated with this information collection.

8. Federal Register/Outside Consultation

MDBG—423.153(d)(5)
In the proposed rule, the ICR burden we are proposing relates to the new requirement for Part D sponsors to contract with LTC facilities to coordinate medication therapy management services with the facilities' monthly medication reviews. We are soliciting comment from the public as to whether this is the best approach for this coordination.

MDBG—483.60(f)
In the proposed rule, certain Indian Health Service and Tribal LTC facilities would be excepted from the ICR burden we are proposing related to the new requirement for LTC consultant pharmacists to be independent of the facility pharmacy, a pharmaceutical manufacturer or distributor, or any affiliate of these entities. However, we are soliciting

public comment on this exception. Additionally, we are proposing in the proposed rule to adhere to the usual effective date of a Final Rule of 60 days after publication for this provision. As a result, the collection burden would be effective in 2011, but we are soliciting public comment on the proposed effective date.

No outside consultations were necessary for this information collection.

9. Payments/Gifts to Respondents

There are no payments/gifts to respondents

10. Confidentiality

The collection of information from the LTC facilities and contracting organizations that pertain to their financial records and submission of data to comply with the proposals have been determined by CMS's Freedom of Information officer to be proprietary and confidential.

11. Sensitive Questions

There are no sensitive questions included in this collection effort.

12. Burden Estimates (Hours & Wages)

MDBG—423.104(d)(4)

We expect a one-time burden to be 12,000 hours per processor to make the initial coding changes necessary to implement this requirement and an annual burden of 250 hours per processor to perform periodic updates of the applicable drugs in their systems. There are an estimated 40 processors. At an average labor cost of $105 per hour for a senior computer programmer, we estimate the first year annual burden associated with this requirement to be 480,000 (12,000 hours per processor x 40 processors) at an estimated cost of $50.4 million (480,000 hours x $105 per hour). After the first fiscal year, the estimated burden associated with this requirement would be 10,000 hours (250 hours x 40 processors) at an estimated total annual cost of $1.05 million.

MDBG—423.153(d)(5)

We expect that complying with this requirement would primarily require the involvement of the parent organization's or the sponsor's general counsel to negotiate, draft and execute the contract. We estimate that complying with this requirement would require 4,812 burden hours (6 burden hours x 802 LTC facilities) for each parent organization or sponsor to execute a contract with a average of 802 LTC facilities at an estimated cost of $402,957 (4,812 burden hours x $83.74 estimated hourly cost). Thus, it would require 1,154,880 hours (4,812 burden hours per parent organization or sponsor x 240 parent organizations or sponsors with Part D LTC residents) for all Part D sponsors to comply with this requirement

at an estimated cost of $96,709,680 ($402,957 estimated cost per parent organization or sponsor x 240 parent organizations or sponsors with Part D LTC residents).

After the first year, we estimate that continued compliance with this requirement would require 1,604 burden hours in each fiscal year (2 hours x 802 LTC facilities) per parent organization or sponsor general counsel to review the contract and, if necessary, execute updated contracts with the LTC facilities at an estimated cost of $134,319 per parent organization or sponsor. Thus, it would require 384,960 burden hours per fiscal year (1,604 annual burden hours per parent organization or sponsor x 240 parent organizations or sponsors with Part D LTC residents) for all Part D sponsors with Part D LTC residents to comply with this requirement at an estimated cost of $32,236,560 ($134,319 estimated cost per parent organization or sponsor x 240 parent organizations or sponsors with Part D LTC residents).

MDBG—483.60(f)

Based on our experience with LTC facilities, we expect that complying with this requirement would primarily require the involvement of the LTC facility's administrator with the assistance of a facility physician, and the director of nursing. We expect also that that the facility's attorney would assist with drafting the contract and reviewing any revisions. We estimate that complying with this requirement would require 16 annual burden hours for each facility to execute a contract with an independent consultant pharmacist at an estimated cost of $1,466. Thus, it would require 251,408 burden hours per fiscal year (16 annual burden hours per LTC facility x 15,713 LTC facilities) for all 15,713 LTC facilities to comply with this requirement at an estimated cost of $23,035,258 ($1,466 estimated cost per LTC facility x 15,713 LTC facilities).

After the first fiscal year, we estimate that continued compliance with this requirement would require 2 annual burden hours (one hour each for the facility administrator and attorney) for each facility to review the contract and, if necessary execute an updated contract with an independent consultant pharmacist at an estimated cost of $192.

13. Capital Costs

All the organizations are going concerns and there are no additional capital or equipment costs resulting from the collection of information.

14. Cost to Federal Government

There are no costs to the Federal Government associated with this requirement.

15. Changes to Burden

MDBG—423.104(d)(4)

The changes in burden are due to a program change associated with a new statutory

requirement.

MDBG—423.153(d)(5)

The changes in burden are due to a program change associated with a new regulatory requirement.

MDBG—483.60(f)

The changes in burden are due to a program change associated with a new regulatory requirement.

16. Publication/Tabulation Dates

There are no publication or tabulation dates. Subsequent PRA packages may include these requirements, which will be addressed, as required, when packages are submitted to OMB for approval.

17. Expiration Date

This information collection contains no forms.

18. Certification Statement

There are no exceptions to the certification statement.

C. Collections of Information Employing Statistical Methods

Not applicable.