Medicare/Medicaid Technical Assistance #83

ISSUE BRIEF

THE MEDICARE PRESCRIPTION DRUG BENEFIT AND FEDERALLY QUALIFIED HEALTH CENTER (FQHC) PHARMACIES

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Introduction


Since the enactment of the MMA, many federally qualified health centers (FQHCs) have been inquiring about how they can participate in the Medicare prescription drug benefit. Many health centers with in-house and contract pharmacies have been able to build a strong medical and pharmacy user base with seniors who did not have Medicare coverage for their prescription drugs. As a result, many seniors turned to health centers for reduced prices on prescription drugs made possible through the sliding fee scale and the 340B discount drug pricing program. Now that Medicare covers prescription drugs for many of these seniors, the question is whether and to what extent health centers can continue providing pharmacy services for these patients.

This Issue Brief is intended to help enlighten health centers about the Medicare Part D prescription drug benefit with particular focus on pharmacy operations. This Issue Brief focuses on the role of the pharmacy in the Medicare drug benefit and will specifically examine issues for FQHCs’ in-house and contract pharmacies.

Background

Pharmacy services are a major service provided by hundreds of health centers across the country. In 2003, 33.5% of all health centers had a licensed pharmacy staffed by registered pharmacists and another 31.9% contracted out for these services. In addition, 61.9% provided pharmacy services through provider dispensing. Health center grantees employ more than 1,400 pharmacy personnel, accounting for nearly 2% of total staff. Pharmacy costs accounted for over $430 million, approximately 7% of health centers total costs, although this percentage is higher among rural health centers. In short, health centers are significant providers of pharmacy services to underserved communities.

Currently, many seniors rely on health centers to help them secure their prescription drugs on sliding fee scales that generally discount the price of services for uninsured patients with incomes below 200% of poverty, using the federal Section 330 grant to make up the difference. Because health centers can purchase prescription drugs through the 340B Drug Pricing Program at discounted prices, many can offer their sliding fee patients deep discounts on prescription drugs.

Approximately two-thirds of health centers participate in the 340B Drug Pricing Program to purchase their pharmaceuticals at statutorily-determined reduced prices. It is estimated that half of these centers own and operate their own licensed in-house pharmacy to fill prescriptions solely for their own patients. Other centers may contract with a local community retail pharmacy to dispense drugs to center patients that the centers purchase at 340B prices, or centers may purchase a limited supply of the most frequently used drugs for provider dispensing at a health center where state law allows this option.
Statutory and Regulatory Provisions in the Medicare Drug Benefit for Pharmacies, including FQHC In-house and Contract Pharmacies

Many FQHC/institutional pharmacies are wondering about their role in the Medicare Part D drug benefit. Fortunately, there are several statutory and regulatory provisions specifically addressing both pharmacy access and reimbursement, and several provisions that provide special consideration for institutional pharmacies, including pharmacies operated by FQHCs. This portion of the issue brief will examine provisions related to pharmacy access and reimbursement under the statute and CMS’ final regulations.

References in this Issue Brief to “FQHC/Institutional Pharmacies” in particular refer to in-house pharmacies, not pharmacies with which FQHCs contract.

NOTICE: You will notice the following the “mortar and pestle” pharmacy symbol throughout the Issue Brief. This symbol will identify when specific action may be required of a pharmacy – either the result of regulations or the function of the program.

Pharmacy Network Requirements on Medicare Prescription Drug Plans

Under the Medicare Modernization Act (MMA), prescription drug plans (PDPs) are the primary mechanism through which Medicare beneficiaries will receive their prescription drug benefits. Unlike the traditional Medicare program, PDPs are private sector Medicare products that organize and deliver prescription drugs through a network of participating pharmacies. PDPs must meet certain standards to operate and must be approved by CMS to participate in the program.

To receive their prescription drugs, Medicare beneficiaries will select a PDP based upon a variety of factors, including drug costs and relative access to local pharmacies. Structurally, the Part D program more closely resembles the Medicare Advantage managed care program, in that beneficiaries must select from among different PDPs to receive their benefits. Beneficiaries can only have their prescriptions filled in those pharmacies that are in the PDP’s pharmacy network. Prescriptions filled at out-of-network pharmacies are allowed only in limited situations.

Therefore, it is important that FQHC/institutional pharmacies join as many PDPs as possible to ensure the broadest scope of access to beneficiaries in their communities. Pharmacies that limit their participation in certain PDPs may unnecessarily deny access to covered prescription drugs to seniors – this is particularly true in underserved areas where there may be a shortage of pharmacies. It is also true that PDPs that exclude FQHC/institutional pharmacies from participation could be denying access to seniors.

PDP Regions

In the winter of 2004, CMS announced the 34 geographic regions for which PDPs can provide prescription drugs to Medicare beneficiaries. The law requires PDPs to provide Part D prescription drug products to all beneficiaries in a region (unless the product is a product for a special population like those residing in long term care facilities or are enrolled in MedicareAdvantage). Congress’ rationale was that by requiring a PDP to cover a statewide or multi-state region, PDPs will build networks in urban, suburban, and rural areas and not just those areas that have a high population density and the opportunity to spread risk.

CMS developed the regions to take into account the following considerations:
- **Eligible Population and Capacity.** CMS sought to design regions to provide a sufficient number of potential enrollees for PDPs. CMS’ research indicated that regions had to be between 400,000 (a minimum number of eligibles for two competing PDPs in a region) and 3 million eligibles.

- **Beneficiary Considerations.** CMS considered how well PDP regions fit with MedicareAdvantage regions to eliminate confusion.

- **Limited Variation in Prescription Drug Spending.** CMS considered state-by-state variations in prescription drug spending, based on data estimating average state prescription drug spending by individuals age 65 and over. CMS sought to minimize the variation in average state prescription drug spending within a region.

Because beneficiaries must select among PDPs to receive their prescription drugs, FQHC/institutional pharmacies that want to participate in the Medicare Part D drug benefit will have no choice but to join the PDP’s pharmacy network available in their region. Pharmacy participation provisions are discussed later in this issue brief.

A PDP Region Map is included in Appendix B.

**Fallback Plans**

*By law, Medicare beneficiaries must have at least two choices of PDPs in their region.* If there are not at least two PDP choices, beneficiaries will have an option to select the “fallback plan” in their area. Fallback plans must offer standard Medicare drug coverage, or its actuarial equivalent. CMS has indicated, however, that fallback plans will not be necessary in any region of the nation.

**Geographic Access Standards**

*The MMA requires that each PDP must meet certain standards to ensure beneficiary access to local pharmacies.* In addition to guaranteeing immediate access to prescription drugs, it was also done to ensure that PDPs did not limit their enrollees to mail-order-only products. These access standards vary depending on the population density of particular geographic areas – urban, suburban, and rural:

1. In urban areas, at least 90% of Medicare beneficiaries in the PDP’s service area must live, on average, within two (2) miles of the retail pharmacy participating in the plan’s network. An urban area is defined as a five-digit ZIP code in which the population density is greater than 3,000 individuals per square mile;

2. In suburban areas, at least 90% of Medicare beneficiaries in the PDP’s service area must live, on average, within five (5) miles of the retail pharmacy participating in the plan’s network. A suburban area is defined as a five-digit ZIP code in which the population density is between 1,000 and 3,000 individuals per square mile; and

If required access is not provided, including through a limited risk plan, the MMA established a fallback process. The Secretary is required to establish a separate process for the solicitation of bids from eligible fallback entities. A single fallback entity may not offer all fallback plans throughout the United States. Fallback prescription drug plans are permitted to offer only standard prescription drug coverage. Beneficiary premiums under fallback plans would be uniform.
3. In rural areas, at least 70% of Medicare beneficiaries in the PDP’s service area must live, on average, within fifteen (15) miles of the retail pharmacy participating in the plan’s network. A rural area is defined as a five-digit ZIP code in which the population density is less than 1,000 individuals per square mile.

There are several important issues for FQHC/institutional pharmacies in these access standards.

- First, FQHC/institutional pharmacies may be counted toward the PDP’s percentages for urban, suburban, and rural areas. This is an important change from the regulation where only retail pharmacies counted toward the access standards.

- Second, PDPs must meet the access standards at the state level in a multi-state region, not the regional level. This is an important change from the NPRM because FQHCs in geographically large rural states (i.e. Montana) won’t be held to the same standards as smaller rural states (i.e. Vermont). CMS reasons that this change may give pharmacies greater negotiating power with PDPs.

**Out-of-Network Pharmacy Access**

*In general, Medicare beneficiaries are required to obtain their prescription drugs through a PDP’s network of pharmacies.* However, there are several exceptions of which FQHC/institutional pharmacies should be aware.

*PDPs are required to guarantee that enrollees have access to prescription drugs outside the PDP’s network* when the enrollee:

- Is traveling outside the PDP’s region, runs out of or loses their drugs or becomes ill and needs a covered drug, AND cannot access a network pharmacy;

- Cannot obtain a covered drug in a timely manner because there is no network pharmacy within a reasonable driving distance that provides 24 hours a day/7 days a week service;

- Must fill a prescription for a covered drug and that drug is not stocked at an accessible network or mail-order pharmacy; and

- Is provided covered drugs dispensed by an out-of-network institutional pharmacy while the patient is in the institutional setting.

If a beneficiary opts to receive their prescription drugs in an out-of-network setting, the beneficiary will pay the out-of-network pharmacy’s usual and customary price at the point of sale, and then file a claim to obtain reimbursement from the PDP.

Although the options for receiving out-of-network services seem broad, PDPs have the authority to place restrictions on access to out-of-network services. *FQHC/institutional pharmacies should understand each PDP’s out-of-network limitations when filling a script for an out-of-network beneficiary.*
The next portion of this Issue Brief will examine the provisions for pharmacies seeking to participate in a Part D prescription drug plan.

Pharmacy Participation in Medicare PDPs

Although the relationships between pharmacies and PDPs are largely unregulated in either the MMA or CMS’ final rules, the law/regulations do provide some protections for pharmacies intended to preserve local access to prescription drugs. The next section of this Issue Brief will look at these provisions related to the participation of pharmacies in PDP’s pharmacy networks.

“Any Willing Pharmacy”

The Medicare Modernization Act provides an “any willing pharmacy” provision for participation in PDP networks. Specifically, new section 1860D-4(b)(1)(A) of the Social Security Act provides…

“A prescription drug plan shall permit the participation of any pharmacy that meets the terms and conditions under the plan.”

In the preamble to their regulations, CMS goes on to clarify that…

“Section 1860D–4(b)(1)(A) of the Act assures pharmacy access by requiring a PDP sponsor to permit the participation of any pharmacy that meets the terms and conditions under the plan. Based on this requirement, we are considering adding the following language to the contract provisions: The PDP sponsor would agree to have a standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy.”

FQHCs’ contract and in-house pharmacies should be aware of this right to participation – while there is no obligation for FQHCs to participate just because they are offered a participation agreement, any FQHC/institutional pharmacy that meets the terms and conditions of the PDP must be allowed to participate in their network.

In addition, FQHC/institutional pharmacies should understand that no PDP can condition “any willing pharmacy” participation by the pharmacy accepting “insurance risk.” Insurance risk is defined as the type of risk accepted by insurers, but does not include payment variations that are intended to improve performance.

“Retail Plus” for FQHC/Institutional Pharmacies

Under the original NPRM, PDPs were not allowed to treat institutional pharmacies (including pharmacies operated by FQHCs) in their pharmacy networks toward compliance with the access standards. This could have created a significant non-regulatory hurdle to FQHC/institutional pharmacies seeking to join a PDP network because FQHC/institutional pharmacies may be a primary pharmacy access point in some of the most rural and underserved communities.
The final rule provides not only that FQHC/institutional pharmacies can participate in PDP’s pharmacy networks, but also that these pharmacies can count toward the geographic access standards described previously. The presence of these supplemental pharmacies, also referred to as “special practice pharmacies”, is described by CMS as “Retail Plus.” “Retail Plus” is a term used in this issue brief and in conversations with CMS staff – it is not included in either the statutory or regulatory provisions and will likely not be recognized by PDPs as such.

The fact that CMS defined “retail pharmacy” to exclude most FQHC/Institutional pharmacies creates special challenges and will require that FQHC/institutional pharmacies actively seek to participate in the networks.

Of course, an FQHC/institutional pharmacy that is also a retail pharmacy does not have to be concerned about participation in the network because they are counted as retail pharmacies. At the same time, such cases raise a whole separate set of concerns, including the fact that a “dual” pharmacy operation of this sort may well require maintaining separate physical inventories under current HRSA/OPA policies, not to mention the fact that, without the 340B discount purchasing advantage, such pharmacies may find that PDP reimbursement levels may well be far below the cost of doing business.

Treatment of “Closed” or “Less-than-Full” Pharmacies (i.e. Provider Dispensaries)

Neither the MMA nor CMS’ final rules provide a standard definition of a “pharmacy” to be included in a PDP’s pharmacy network. As such, the PDP has the discretion about what entity constitutes a “pharmacy” for the purpose of network participation.

Most pharmacies operated by FQHCs are “closed,” meaning that only patients of the health center can use the services of that pharmacy. This is largely the result of the requirements of the 340B discount drug program. Likewise, many FQHCs have what are described in this Issue Brief as “less-than-full” pharmacies. These pharmacies may be limited to provider dispensaries or could have state licensure that allows them to operate in an untraditional pharmacy manner. A “dispensary” is a health center where prescription drugs are dispensed by a prescribing provider.

Again, because CMS does not provide a standard definition of “pharmacy,” there is no statutory prohibition against an FQHC “closed” or “less than full” pharmacy from participating in a PDP’s pharmacy network. However, pharmacies must comply with the terms and conditions of the PDPs – these conditions could limit inclusion of closed or “less than full” FQHC pharmacies in a network. However, if an FQHC/institutional closed pharmacy is denied access to a PDP because the PDP requires that pharmacies provide services to all users, the FQHC should seek to negotiate with the PDP to create an exemption for the class of FQHC/institutional pharmacy that is required by law to provide prescription drugs only to their patients. The FQHC can stress that CMS regulations allow for the participation of FQHC/institutional pharmacies and the PDP has the authority to include this class of pharmacy in their network.

Understanding the opportunities for FQHC/institutional pharmacies to participate in the Medicare Drug benefit, the next section of this Issue Brief will look at the statutory and regulatory provisions impacting pharmacy operations.
Programmatic and PDP Provisions Impacting Pharmacy Operations

Although the MMA and the regulations impose relatively few obligations on pharmacies, there are several rules applying to PDP operations under the Part D benefit that will create certain requirements on participating pharmacies. The following provisions will likely have an impact on the way that pharmacies operate and FQHCs should be aware of them.

Formularies

A PDP may offer prescription drugs through a formulary. A formulary is a restricted list of drugs that are covered by a health insurance issuer. Generally, drugs that are not on the formulary are not covered by health insurance issuer (and thus must be obtained out of pocket by the enrollee) or require higher co-payments from plan enrollees. Formularies are widely used in the private sector to limit utilization of prescription drugs for plan enrollees and control prescription drug costs.

The MMA and final rules establish certain standards for a PDP’s formulary. Under the Part D benefit, the formulary must provide:

- The types of drugs most commonly needed by enrollees as recognized by national treatment guidelines and be approved by CMS;
- At least two drugs (not therapeutically- or bioequivalent) within each therapeutic category and class of drugs, unless only one Part D drug exists in a particular therapeutic category and class; and
- Only one drug will be allowed in a category or class if it is clinically superior to another drug in that category or class.

In recent guidance on this issue and in the negotiations with insurers, however, CMS has indicated that insurers must cover “all or substantially all” of the drugs in six classes that are often prescribed for Medicare beneficiaries: antidepressants; antipsychotics; anticonvulsants; H.I.V. drugs; cancer medications; and immunosuppressants.

It is important for FQHC/institutional pharmacies to understand that, although each PDP has certain minimum requirements on its formularies, theoretically each PDP may offer a different set of “covered” drugs under the Medicare drug benefit. FQHC/institutional pharmacies will have to know the coverage requirements under each contracting PDP’s formularies and integrate them into the pharmacy practice. This is potentially a very difficult and challenging area, as it may be difficult, if not impossible, to accommodate multiple formularies in many cases.

Drug Utilization Management Programs

Each PDP is required to maintain a drug utilization management (DrUM) program. These programs are intended to manage the use of prescription drugs and ensure that medications are used appropriately.

There are relatively few statutory and regulatory requirements on DrUMs. The rules require that PDPs must:
1. Maintain a program that includes incentives to reduce costs where medically appropriate;

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

3. Provide CMS with information concerning the procedures and performance of a program according to CMS’ guidelines.

It is reasonable to assume that many PDPs will require network pharmacies to participate in their DrUM and that there will be certain requirements on these pharmacies. Most likely, these requirements will include the use of data reporting systems and other mechanisms to track drug use among beneficiaries. Each PDP will have specific requirements on pharmacies, and FQHCs should familiarize themselves with these requirements.

Medication Therapy Management Services

The MMA provides for a new Medicare “service” known as Medication Therapy Management (MTM) services. Unlike the traditionally defined Medicare service, this service must be provided by a PDP but is not clearly defined by the law or regulations and the definition of services and levels of reimbursement may vary from one PDP to another.

Nonetheless, FQHCs are in an excellent position to provide MTM services because they are limited to only certain Medicare beneficiaries that are health center patients. MTM services are limited to PDP enrollees that have multiple chronic diseases (such as diabetes, asthma, congestive heart failure, or hypertension [to be determined by PDP]), are taking multiple Part D covered drugs, and are likely to incur annual costs for covered drugs that exceed $4,000. Many FQHC patients and pharmacy users are likely to be eligible for MTM and FQHCs should ensure that they understand the opportunities available from their PDP to provide these services.

Level Playing Field between Mail-Order and Network Retail Pharmacies

The MMA and final rules require what is called a “level playing field” between “mail-order” and “brick and mortar” pharmacies whereby beneficiaries can obtain a 90-day supply of prescription drugs through the local retail pharmacies. However, a PDP may require an enrollee to pay higher cost sharing for the 90-day supply, and reimbursement levels for the longer supplies may be considerably lower.

Because many FQHC/institutional pharmacies are not retail pharmacies, it would appear that participating non-retail FQHC pharmacies would not have to meet this requirement. However, CMS should clarify this question for FQHCs and other institutional pharmacies.

Treatment of Generic Drugs
Given concerns about the costs of prescription drugs under the program, Congress and CMS have sought ways to promote the use of less costly generic drugs. However, there is no requirement that PDPs prescribe a generic alternative to a brand-name prescription drug when a generic alternative is available.

Instead, **Part D sponsors must ensure that their network pharmacies inform enrollees of the difference between the price of a Part D drug and the price of its lowest priced generic version available at the pharmacy.** For non-mail order pharmacies, this price differential must be given to enrollees at the time of the drug purchase. CMS has the option to waive this notification requirement in certain situations.

CMS’ definition of “generic drugs” does not include “multiple source” drugs — also known as “off-patent innovator drugs.” Therefore, network pharmacies are not required to notify patients if the costs for an alternative multiple source drugs are lower. However, PDPs are encouraged by CMS to provide this information to enrollees as desired, and thus an FQHC/institutional pharmacy may be required to or asked to provide this information by the PDP.

**Provider/Pharmacy Promotion of PDPs**

*The provisions regarding promotion of Medicare Part D and PDPs apply both to the FQHC as a medical provider and the FQHC as a pharmacy provider, and should provide opportunities and insights for FQHCs.*

**Pharmacy:** CMS’ regulations will allow Part D sponsors to use participating pharmacies to market their plans to beneficiaries. However, CMS will require a contractual agreement for any Part D sponsor doing so to offer beneficiaries information on all Part D options available in the service area.

**Provider:** If a FQHC provider (the medical portion of the health center) accepts remuneration in exchange for promoting particular PDPs, it could only do so if such arrangement is in compliance with federal and state fraud and abuse laws.

FQHCs should take two important lessons from this guidance. First, FQHCs as providers can promote the Medicare Part D program without fear of conflict of interest or fraud and abuse with their pharmacy, as long as they are promoting all options and complying with Federal fraud and abuse laws. The provider must promote all programs in its service area equally and cannot promote any particular program, thereby helping it maintain its unbiased perspective as a trusted third party provider of information to the beneficiary.

Second, the FQHC as pharmacy should maximize its participation in as many PDPs as are available to ensure that it does not lose pharmacy users as a result of the unbiased guidance offered by the outreach and enrollment staff on the provider side. An FQHC/institutional pharmacy should seek to join as many PDPs pharmacy networks as possible to ensure that is offering the most opportunities for its patients to select the best PDP for them.

**Waiver of Co-payments**
The Medicare Modernization Act modified Section 1128A of the Social Security Act governing fraud and abuse restrictions on health care providers delivering care through Federal health programs. Specifically, this section provides for the waiver of Medicare Part D co-payments in certain situations. In their preamble to the final rule, CMS states:

“...[p]harmacies are permitted to waive or reduce cost sharing amounts provided they do so in an unadvertised, non-routine manner after determining that the beneficiary is financially needy or after failing to collect the cost-sharing amount despite reasonable efforts, as set forth in section 1128A(i)(6)(a) of the Act. In addition, a pharmacy may waive or reduce a beneficiary’s Part D cost-sharing without regard to these standards for beneficiaries enrolled in a Part D plan eligible for the low-income subsidy, provided the pharmacy has not advertised that the waivers or reductions of cost-sharing are available. Depending on the circumstances, pharmacies that waive or reduce cost sharing amounts for covered Part D drugs without following the requirements of the pharmacy waiver safe harbor could be subject to civil monetary penalties and exclusion from participating in Federal health care programs, as well as criminal fines and imprisonment under the anti-kickback statute.”

Although this waiver language seems straightforward, FQHCs—as 330 grantees or FQHC look-alikes-- must also be aware of relevant requirements of the Public Health Service Act (PHSA) if they waive the cost sharing for their Part D users. Specifically, Section 330(j)(3)(F) of the PHSA provides that:

“(F) the center has made or will make and will continue to make every reasonable effort to collect appropriate reimbursement for its costs in providing health services to persons who are entitled to insurance benefits under [MEDICARE]...”

and

“(G) the center -

(ii) has made and will continue to make every reasonable effort -

(II) to collect reimbursement for health services to persons described in subparagraph (F) on the basis of the full amount of fees and payments for such services without application of any discount;”

This PHSA requirement could put FQHCs at a disadvantage with other network pharmacies since any cost-sharing amount can be a barrier to low-income seniors. Thus, a retail pharmacy can waive the cost-sharing for low-income beneficiaries, while an FQHC pharmacy may have some grant limitations in its ability to fully waive cost sharing for some beneficiaries. The impact on FQHCs may be minimal, however, since, under 330 grant requirements health centers can only collect a nominal co-payment from those with income under 100% of the Federal Poverty Line (FPL) and must apply a sliding scale discount on co-pays from beneficiaries whose income is between 100%-200% of the FPL.

Although a similar issue arose under the Medicare-approved discount drug card program, HRSA did not change its policy with respect to the collection of cost sharing for drug card enrollees either. This issue may again cause problems in the Medicare Part D drug benefit, although close observers see little likelihood that retail pharmacies will regularly waive cost-sharing amounts.
Reimbursement Opportunities under the Medicare Part D Benefit

FQHC/institutional pharmacies that participate in the Medicare Part D prescription drug benefit will have several new opportunities to generate revenues for the health center. The next section of this Issue Brief will look at revenue opportunities and challenges under the Medicare drug benefit.

Acquisition Rates and Dispensing Fees

There are no requirements in either the law or regulations governing the payment of acquisition costs or dispensing fees to a PDP’s network pharmacies. In repeated conversations with CMS, CMS affirmed that they will not interfere in the reimbursement negotiations between network pharmacies and a PDP. Therefore, it will be dependent on the FQHC/institutional pharmacy to negotiate the best rates as possible with the PDP – a real challenge in its own right, as many, if not most, PDPs can be expected to offer contracts on a “take-it-or-leave-it” basis.

Medication Therapy Management Services

For the first time since the program was created, the drug management services of a pharmacist or other named provider will become a Medicare reimbursable service. Medication Therapy Management Services (MTMS) gives FQHC/institutional pharmacies an opportunity for the employee pharmacist to generate new revenues for the FQHC. This can help FQHCs defray the costs of their pharmacy operations, where current expenditures may constitute a drain on the FQHC’s operating funds.

FQHCs that currently do not have an in-house pharmacy may want to consider the revenue impact of MTM in making a determination about whether to open a pharmacy as part of the FQHC.

No Eligibility for Wrap-Around Payments

While the MMA added a requirement that CMS make ‘wrap-around’ payments to any FQHC that contracts with an MA plan, these wrap-around payments do not apply to pharmacy services provided by an FQHC in a PDP. According to CMS’ interpretation of the law, FQHCs are not entitled to a wrap-around for two reasons. First, a “pharmacist” is not a core provider of service as identified under Medicare Part B. Second, the wrap-around provided in the MMA only applies to services provided under Medicare Part C, the MedicareAdvantage program (Part C incorporates only the services covered under Parts A and B). Because the prescription drug benefit is under Medicare Part D, the wrap-around does not apply to these services.

However, there may be a need for some clarification about the wrap-around with respect to the delivery of Medicare prescription drugs under a MA-PD. Theoretically, if a MA-PD allows an FQHC-core provider (i.e. a nurse practitioner) to deliver certain pharmacy-related services like MTMS, an FQHC would be entitled to MA wrap-around payments. CMS should clarify what occurs in this event.

Preferred v. Non-Preferred Pharmacy Status
Although the law provides for “any willing pharmacy” participation within a PDP’s pharmacy network, the regulations also allow a PDP to differentiate between so-called “preferred” and “non-preferred” pharmacies. The preamble to the proposed rule gives CMS’ justification for the creation of this distinction:

“Section 423.120(a)(5) of our proposed rule, based on section 1860D–4(b)(1)(B) of the Act, clarifies that a PDP sponsor... would have the option of reducing cost-sharing for its enrolled beneficiaries below the level that would otherwise apply for covered Part D drugs dispensed through network pharmacies. We interpret this provision as not restricting PDP sponsors... from varying cost-sharing not only based on type of drug or formulary tier, but also on a particular pharmacy’s status within the plan’s pharmacy network— in essence authorizing distinctions between ‘’preferred’’ and ‘’non-preferred’’ pharmacies. We believe that the statute allows these within network (preferred versus non-preferred pharmacy) distinctions to be made despite the ‘‘any willing provider’’ provision at § 423.120(a)(4)(i) of our proposed rule.

The “non-preferred status” may pose a very serious challenge for FQHCs. Because most health center patients have low-incomes, a pharmacy’s “preferred/non-preferred” status (and the reduction in cost sharing that comes with that status) may be the deciding factor in whether an enrollee patronizes the pharmacy. Because PDPs are allowed to “discriminate” in favor of certain pharmacies through a preferred status designation, FQHC pharmacies should be very cautious about being deemed as a “non-preferred” pharmacy.

Treatment of Prescription Drug Coverage under Medicare Advantage

Unlike beneficiaries in the traditional Medicare program, known as Medicare Parts A and B, those beneficiaries who receive their Medicare benefits through a managed care plan (also known as a Medicare Advantage, or MA, plan) have a different mechanism for receiving their prescription drugs. It is important for FQHCs to understand this difference, lest a beneficiary of an MA plan seek to obtain services from the FQHC that is not a participating MA-PD provider.

Under the Medicare Modernization Act, an enrollee of a MA plan must obtain their prescription drugs through a Medicare Advantage Prescription Drug Plan (also known as MA-PD), unless they are enrolled in an MA fee-for-service plan that does not provide prescription drug coverage or in a Medicare Advantage medical savings account (MSA). This is intended to ensure continuity of care within the Medicare Advantage plan.

Therefore, any FQHC/institutional pharmacy that wants to provide pharmacy services to its MA users should ensure that it is a part of the MA-PD for that MA plan. Pharmacists may want to check with the medical practice to determine if they are an MA network provider and whether the FQHC pharmacy can join the network of the MA-PD.

The Role of the 340B Prescription Drug Program and the Part D Drug Benefit

Understandably, the biggest question from FQHC/institutional pharmacies with the onset of the Medicare drug benefit is how the new benefit will interact with the existing 340B prescription drug program. This question was resolved under the Medicare-approved discount drug card in a manner that
allowed FQHCs and other “covered entities” to participate in the program and continue providing discounts via the 340B program through the drug card.

*At the time of the publication of this Issue Brief, there is nothing that prevents 340B covered entities from participating in the Medicare Part D drug benefit (provided they meet the terms and conditions of the PDPs) and continuing to use the 340B program to acquire drugs solely for their patients. Neither CMS nor HRSA’s Office of Pharmacy Affairs has changed the way in which the 340B program operates with respect to the Medicare Part D benefit. As with current law, FQHCs and other covered entities cannot acquire prescription drugs through the 340B program for pharmacy users that are not patients of the FQHC. They must comply with all of the requirements currently in operation under the 340B program. Of course, nothing prevents an FQHC pharmacy that is a full retail pharmacy and providing prescription drugs to non-FQHC patients in the community provided they comply with 340B restrictions.*

Both Medicaid and Section 340B legislation prohibit a duplicate discount or rebate from the manufacturers for the same drug. To avoid a duplicate discount, Medicaid agencies will only reimburse 340B entities their actual acquisition cost plus a reasonable dispensing fee for drugs provided to Medicaid recipients. Often these dispensing fees are inadequate, resulting in many health centers simply not providing their 340B discounted drugs to their Medicaid patients. However, unlike Medicaid, *there is no statutory prohibition in either Medicare law or Section 340B of the Public Health Service Act against a covered entity using the 340B program in connection with the Medicare Part D prescription drug benefit.* This is particularly important with the transition of the dual eligibles’ Medicaid prescription drug coverage to Medicare – for the purposes of Part D drug coverage for dual eligibles, they are treated as Medicare beneficiaries for prescription drugs, not Medicaid beneficiaries. As such, the Medicaid prohibition doesn’t apply.

In a description of the impact of 340B on the Part D benefit with respect to Indian Health Service (IHS) Pharmacies, CMS states with respect to “Acquisition of Pharmaceuticals,”

“...Federally Qualified Health Centers and after approval of the Health Resources and Services Administration Office of Pharmacy Affairs, are eligible to order medications at 340B Drug Pricing. Because IHS acquires drugs through federal supply sources, this may impact a Medicare Part D sponsor’s ability to negotiate rebates from manufacturers for these medications purchased by the Indian/Tribal/Urban clinics and dispensed to the plan members.”

Every communication between this author and CMS has affirmed that CMS will not get involved with any covered entity that integrates the 340B discount program into the Medicare Part D program. This is consistent with guidance provided by CMS under the Medicare-approved discount drug card and, at this time, there is no reason to believe that this will be changed before the implementation of the Part D program.

**The Importance to FQHCs of Retaining Medicare Pharmacy Users and the Potential Impact that the Part D Drug Benefit May Have on Health Centers’ Operations**

The single largest threat posed by Medicare prescription drug benefit for health centers with either in-house or contracted pharmacies is the possibility that FQHC’s Medicare patients will begin using another health care provider because they no longer have to be a patient of the clinic to receive affordable prescription drugs. This has a doubly negative effect on the FQHC – it will reduce Medicare revenues to the medical practice and will reduce users of the pharmacy. As a result, the Medicare drug benefit could have a dramatically negative effect on health centers and steps should be taken to reduce or eliminate this impact on FQHCs.
It is vital for FQHCs to consider the following issues with respect to the Medicare drug benefit:

**Preserving Access to Prescription Drugs in Underserved Areas**

Because the FQHC/institutional pharmacy may be the only pharmacy access point for beneficiaries in a community, FQHC participation is more than simply a question of financial cost/benefit for the health center – it is a matter of providing necessary services to people in need in the community. An FQHC that chooses to not participate in the Part D benefit may, however unintentionally, have the effect of denying the prescription drug benefit to needy Medicare beneficiaries in their communities.

**Maximizing PDP Participation**

To ensure that FQHCs continue to be the pharmacy resource of choice for Medicare beneficiaries in their communities, FQHC/institutional pharmacies should be as aggressive as possible in joining Medicare prescription drug plans. Although CMS is not announcing the names of the entities that are applying to be PDPs, they are giving pharmacies and other entities that want to contract with PDPs an opportunity to make themselves known to those who may be offering a prescription drug plan.

To accomplish this, FQHC/institutional pharmacies can download a form and submit it to CMS from CMS’ website at www.cms.gov/pdps. We have also attached a copy of the form to this Issue Brief. This form allows a check-box for FQHC and other safety net pharmacies. We recommend that FQHCs complete these forms and return them to CMS as soon as possible.

Although it is important that FQHCs join PDPs, it is equally important that FQHCs not accept agreements that are not in their financial interest. Although only individual FQHCs can determine what is in their financial best interests, FQHCs should avoid cutting deals with PDPs out of desperation or confusion or simply because FQHCs can acquire prescription drugs through the 340B program.

**Maximizing or Maintaining Medicare Revenues**

In general, FQHCs face challenges in attracting and retaining senior Medicare beneficiaries to their practice. For patients between the age groups of 60 and 64 (when many of these patients are uninsured) and 65 and 69 (when these patients are eligible for Medicare), FQHCs witness a fairly significant drop in users in these categories. Although there are several reasons for this, this drop off could be exacerbated by the dis-linking of affordable prescription drugs and being a medical user of the FQHC.

As such, if a senior can receive affordable prescription drugs from any pharmacy, they may also seek to go to a different physician for their medical services. This could seriously impact Medicare revenues coming into the health center. Therefore, FQHCs should look for ways to retain their medical AND pharmacy users during and after the transition on the new Medicare prescription drug benefit.
Attracting New Users to the FQHC/Pharmacy

The Medicare Part D drug benefit may give FQHCs an opportunity to attract new senior patients into the health centers’ medical and pharmacy practices. The close interaction that FQHC’s employed pharmacists and physicians have in care coordination and drug management give FQHCs a clear advantage by ensuring effective communication on behalf of the patient.

In addition to the improved communication between the patient’s physician and pharmacist, there are other benefits that the patient can receive in visiting an FQHC, including the waiver of the Medicare Part B deductible and authority to use sliding-scale discounts on Part B co-payments. FQHCs should consider the Part D drug benefit as an opportunity to build their patient base among a currently underserved population within health centers nationwide.

Changing the Pharmacy Practice

Participation in the Medicare prescription drug benefit may require FQHCs to expand or modify their pharmacy practice from its current status. For example, FQHCs that don’t have a pharmacy may want to consider offering in-house or contract pharmacy services to their patients (Medicare and others). FQHCs that have provider dispensaries may want to consider hiring a full-time pharmacist. FQHCs with closed pharmacies may want to consider expanding their services to become full retail pharmacies (while maintaining their commitment to the uninsured through the 340B program). FQHCs may want to use the creation of the Medicare drug benefit to change their thinking about providing pharmacy services to their patients.

In short, although there are other lessons to be learned, there are clearly several financial and service reasons for FQHCs to consider participating in the Part D benefit.

Conclusion

The Medicare Modernization Act provides for the biggest change in a Federal health entitlement program since Medicare and Medicaid were first created in the mid-1960s. The addition of hundreds of billions of dollars for the new benefit, the dramatic changes in the benefits-delivery mechanism, and the significant disruption of these changes will force a fundamental change in the way the health care system works. It is no different for federally qualified health centers.

The MMA poses numerous opportunities and challenges for FQHC pharmacies. The opportunities include:

1. Generating new or protecting existing sources of Medicare and pharmacy revenue for the FQHC;

2. Expanding services at the FQHC and to community residents;

3. Maintaining a level of service to existing patients; and

4. Attracting new medical and pharmacy users to the health center.
Although there are opportunities, challenges also exist…

1. *FQHCs will have to find new ways to retain patients in the medical practice given that low-income Medicare patients will no longer have to rely on the FQHC in order to receive affordable prescription drugs;*

2. *FQHCs may have to change their pharmacy operations to open their services to more people in their communities, requiring the hiring of new pharmacy staff, and purchasing or upgrading facilities and equipment; and*

3. *FQHCs may have to build new relationships with local providers and pharmacies and look for ways to attract new patients to the health center.*

What is certain is that the Medicare prescription drug benefit will have significant impact on FQHCs with pharmacies and FQHCs will be forced to adapt their behavior or accept the changes in their practice that this new benefit will bring.

**Appendices**

Appendix A – Glossary of Terms  
Appendix B – Map of PDP Regions  
CMS Part D Notification Form
# Appendix A: Glossary of Terms and Quick Definitions

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>CMS</td>
<td>The Centers for Medicare and Medicaid Services, the Federal agency that oversees the Medicare program</td>
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<tr>
<td>FQHC</td>
<td>Federally qualified health center</td>
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<tr>
<td>MA</td>
<td>Medicare Advantage, the Medicare managed care program</td>
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<td>MA-PD</td>
<td>A Medicare Advantage plan that includes coverage of the new Part D drug benefit for its Medicare enrollees</td>
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<tr>
<td>MMA</td>
<td>Medicare Modernization Act of 2004, the law that created the Medicare prescription drug benefit</td>
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<tr>
<td>NPRM</td>
<td>The Medicare Part D proposed rules (published August 2004) – the NPRM was modified by the Final Rules published in January 2005</td>
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<tr>
<td>Part D</td>
<td>The portion of the Medicare law that created the Medicare prescription drug benefit</td>
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<tr>
<td>Part D Sponsor</td>
<td>A company offering a Prescription Drug Plan</td>
</tr>
<tr>
<td>PDP</td>
<td>Prescription Drug Plan, a plan that offers only Part D coverage for Medicare beneficiaries (who remain in traditional Medicare fee-for-service)</td>
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Appendix B: Map of PDP Regions

PDP Regions

Note: Each territory is its own PDP region.
### Interested in Part D Contractors

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<th>Organization Name:</th>
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<td>Address:</td>
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<tr>
<td>Website:</td>
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**Please select one of the following categories:**

**Pharmacy**
- [ ] Long-Term Care
- [ ] Home Infusion
- [ ] I/T/U
- [ ] Mail Order
- [ ] Retail
- [ ] 340B, FQHC, or other safety-net provider

**Consultants/Implementation Contractor**
- [ ] Accounting/Business Services Firm
- [ ] Actuarial Service Firm
- [ ] Call Center
- [ ] Information Technology Firm
- [ ] Law Firm
- [ ] Marketing Firm
- [ ] Pharmacy Benefit Management
- [ ] Other

- [ ] Pharmaceutical Manufacturer

- [ ] Other

Note: CMS will not post information that does not come back on the above chart, unless special arrangements have been made with Trish Axt at TAxt@cms.hhs.gov or Lisa Mack at MMack@cms.hhs.gov