Information for Part D Sponsors on Contracting with Safety Net Pharmacy Providers

OVERVIEW

The purpose of this overview is to provide basic information to help Prescription Drug Plans (PDPs) and Medicare Advantage Prescription Drug Plans (MA-PDs) understand the important role that safety-net providers play in ensuring access to care, including provision of prescription drugs, to Medicare beneficiaries. There are approximately 6.3 million Medicare beneficiaries who currently receive prescription coverage through their state Medicaid programs, all of whom will have that coverage replaced with the Medicare prescription drug benefit on January 1, 2006. In addition, a majority of Medicare beneficiaries served by safety-net provider organizations have limited incomes.

Below you will find information about the role of safety-net providers and, in particular, those safety-net providers that the federal Health Resources and Services Administration (HRSA) supports either through grant funds or through the 340B Drug Pricing Program in providing access to health care services.

Attachment A of this document provides sample language that was developed to facilitate the negotiation of contracts between PDPs and MA-PDs and safety-net pharmacy providers. The model language is not intended to address all possible safety-net providers and/or related concerns but rather is provided as a basis to ease the negotiation process between these parties given the importance of these providers in ensuring continuity of care for those beneficiaries in greatest need.

WHAT ARE SAFETY NET PROVIDERS

Safety net providers are defined by the Institute of Medicine (IOM) as "providers that by mandate or mission organize and deliver a significant level of health care and other health-related services to the uninsured, Medicaid, and other vulnerable patients."

These providers have two distinguishing characteristics: (1) by legal mandate or explicitly adopted mission they maintain an "open door," offering access to services to patients regardless of their ability to pay; and (2) a substantial share of their patient mix is uninsured, covered by Medicaid, or are otherwise vulnerable patients. These core safety net providers typically include federal, state, and locally supported community health centers (CHCs) or clinics, many of which are deemed Federally Qualified Health Centers (FQHCs), public hospital systems, and local health departments. In some communities they also include mission-driven teaching hospitals, community hospitals and ambulatory care clinics (which are often located in central city areas or serve as the sole provider of health care in the community). Rural health clinics (RHCs), small rural hospitals, critical access hospitals (CAHs), clinics that receive Ryan White HIV/AIDS grant funding, and nurse managed clinics also are important examples of key components of the safety net.

All Part D sponsors are required to form networks of willing pharmacies in the sponsors' service area to meet the prescription needs of program recipients beginning on January 1, 2006. Pharmacies operated by or within safety net organizations are valuable assets to patients because they permit the patients to "stay home" for their pharmacy care and not be separated from familiar services and trusted care-givers in order to take advantage of the new Part D Medicare prescription benefit. Part D and the sponsors will benefit from relationships with safety net pharmacies that educate their patients as to the value of Part D and encourage and help them to find and select a sponsor appropriate to their needs. Initially the details of this new program may prove overwhelming to many potential participants. Guidance from trusted professionals can go a long way in easing the process.

PHARMACY SERVICES

Many of these providers offer access to prescription drugs and pharmacy services to their own patients and not to the public at large. This access may be provided through a "closed pharmacy" – one that is not open to the general public. These pharmacies are typically smaller and less visible to the public than more commonly identified retail pharmacies.

Pharmacists in these settings serve a major role in improving the health outcomes of the facilities' patients. Patients who consider the facility their "medical home" depend on "their" pharmacy. These pharmacies may however be open fewer hours, have more limited formularies, and less working space than more traditional pharmacies. It should be noted that while contracting with these pharmacies will help improve access for these beneficiaries, "closed pharmacies" do not count towards meeting retail network access standards under the Part D benefit as required by CMS. However, CMS created an incentive for Part D plans to contract with certain safety-net providers – FQHCs and RHCs – by allowing them to count these pharmacies toward their retail pharmacy networks.

THE 340B DRUG PRICING PROGRAM

An estimated 12,000 safety net providers participate in HRSA's 340B Drug Pricing Program, which allows them to buy their prescription drugs at significantly discounted prices. Participation in the 340B Program can enable pharmacies to provide prescriptions to their patients at lower-than-market price. The 340B price is calculated by pharmaceutical manufacturers for each of their products based on a formula stipulated in section 340B(a)(2) of the Public Health Service Act. Any covered entity, also specified in the law, which is registered with DHHS/HRSA's Office of Pharmacy Affairs, (www.hrsa.gov/opa) may purchase drugs at these lower prices. (A database of 340B participating providers can also be found at this website.) Participation in the 340B Program should have no bearing on their acceptability as network participants with Part D sponsors.

ADDITIONAL INFORMATION

Federally Qualified Health Centers, Disproportionate Share Hospitals, and Rural Health Clinics are important examples of safety-net providers. Additional background on these provider types is provided below:

Federally Qualified Health Centers & Their Pharmacies

Federally Qualified Health Centers are certain local, public or non-profit, community-based safety net health care providers, most of which have been funded by the Department of Health and Human Services to provide comprehensive low cost health care to medically underserved areas and populations regardless of their insurance status or ability to pay. FQHCs include Public Health Service Act Section 330-funded health centers, Federally Qualified Health Center "Look-Alikes" which do not receive federal funding, and outpatient health programs or facilities operated by tribes or tribal organizations or urban Indian clinics under title V of the Indian Health Care Improvement Act. The Indian Health Service, Tribes or Urban Indian Programs (I/T/U) are addressed independently in the Part D regulations.

Across the nation, FQHCs play an integral role in ensuring access to primary and preventive services to seniors living in underserved areas. In 2003, FQHCs funded under Section 330 of the PHS Act provided care to more than 12.4 million people, of which 896,000 were Medicare beneficiaries. FQHCs deliver low cost, high quality pharmaceutical services to patients to meet the needs of Medicare beneficiaries. It is important that Medicare patients currently served by FQHCs be able to take advantage of the Medicare Part D prescription drug benefit at their respective in-house or contract FQHC pharmacy. Connecting FQHCs into the sponsors' networks will allow beneficiaries to receive seamless care and support the FQHCs' efforts to continue serving the rapidly growing elderly population. The current Presidential Health Center Growth Initiative will increase the number of health center patients to 16 million and the percentage of Medicare users is also likely to increase.

There are two ways that Health Centers make prescription drugs available to the approximately 896,000 Medicare beneficiaries they see:

1) Licensed, in-house (closed) pharmacy owned and operated by the health center - approximately 300 health centers, many with multiple sites, purchase and dispense drugs through their own state-licensed pharmacies, which are supervised by a pharmacist. Many centers are able to purchase drugs at 340B Program prices for all of their patients and fill prescriptions for their patients on site.

2) Contracted pharmacy arrangements - approximately 435 sites have an agreement with local retail pharmacies or chains to dispense drugs purchased by the 340B- participating health center to health center patients in exchange for a dispensing/administrative fee. The health center purchases the drugs from a wholesaler, has them shipped to the retail pharmacy with which the center has a written agreement for dispensing and related

services, and the center is invoiced for and pays for the drugs. The retail contract pharmacy keeps track of the center's inventory, places reorders, dispenses drugs to center patients, collects co-pays, and generates reports to the center on a set periodic basis. The retail pharmacy is not restricted from filling prescriptions for the general public. However, they cannot use drugs purchased through the 340B Drug Pricing Program to fill prescription for the general public who are not patients of the health center.

Prescription drugs in both types of pharmacy arrangements are acquired through normal trade channels, i.e., from manufacturers and wholesalers.

Disproportionate Share Hospitals (DSH)

A disproportionate share hospital (DSH) that participates in the 340B Drug Pricing Program must either be owned or operated by state or local government or have a contractual relationship with a state or local government to provide care to low-income populations.

Over 200 DSH hospitals serving low-income patients qualify for 340B drug pricing.

Although 340B participating hospitals constitute less than 5 percent of all hospitals in the United States, they provide over 25 percent of uncompensated health care for Americans.

The 340B-participating DSH hospitals provide outpatient services to almost two million Medicare patients, particularly low-income patients who often lack pharmaceutical coverage. 340B hospital pharmacists are in a unique position to educate their patients about the new prescription drug program, to help them select the most appropriate plan based on the relationship between the patients' medications and the plan formularies, to monitor drug utilization, and to ensure compliance. Most 340B hospital pharmacies are likely to already meet standard Pharmacy Benefit Management participation requirements; many have existing agreements with PBMs and managed care networks.

Rural Health Clinics

Rural Health Clinics (RHCs) were established by Public Law 95-210 in 1977 for the purpose of improving access to primary care for Medicare and Medicaid beneficiaries in rural communities. RHCs can be public, private, or non-profit. The main requirements to obtain RHC status include:

1. The clinic is located in a rural area that is designated by the U.S. Census Bureau and by the Secretary of Health and Human Services as either a Health Professional Shortage Area (HPSA), or Medically Underserved Area (MUA), generally determined by information from the State Health Department.
2. The clinic must employ a mid-level practitioner at least 50% of the time the RHC operates. Examples include a physician assistant, certified nurse mid-wife, or nurse practitioner.
3. Must provide outpatient primary care.

4. Clinic must be under the medical direction of a physician who must be on site at least once every two weeks.
5. Must provide six basic lab tests on site.
6. Must be clean and handicapped accessible.
7. Must have a current and applicable policy and procedures manual.
8. Drugs and samples must be stored safely.
9. Adequate medical records must be maintained for six years.

More Information

You can visit www.hrsa.gov or http://www.ask.hrsa.gov/ for more information about these providers. If you have specific questions, you can email Dr. Regan Crump at rcrump@hrsa.gov.