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The Inside Source on the Public Health Service 340B Drug Discount Program

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CMS and HRSA To Collaborate on Medicare Part D Outreach

Agencies to Develop Special Resources for Safety Net Pharmacies

The Centers for Medicare and Medicaid Services (CMS) and the Health Resources and Services Administration (HRSA) announced on May 4 that the agencies plan to introduce a new set of tools and resources aimed specifically at assisting 340B and other safety-net providers in preparing for the upcoming launch of the Medicare Part D prescription drug benefit.

During a CMS-sponsored Open Door Forum conference call on low-income health access, officials from CMS and HRSA said that their agencies plan to host a new website for pharmacists that will include a specific focus on 340B providers and develop draft language for 340B and other safety-net providers that wish to contract with potential Part D plans.

The two agencies have developed a Medicare website for pharmacists and sample contract language for 340B providers who wish to contract with Part D drug plans.

"HRSA is committed to continue working with CMS to support efforts to get the word out about the new prescription drug benefit to HRSA-funded partners," said HRSA's Rebecca Hines, adding that many of the questions that HRSA is receiving on the new benefit have come from 340B providers.

According to Hines, the agencies will be launching a new pharmacy website that will include specific information for "special practice pharmacies" such as 340B providers and other safety-net institutions. The site should be operational in a matter of weeks.

Hines also said that CMS and HRSA are planning to release "sample addendum language" for safety net providers that wish to contract with Part D plans to become part of their pharmacy networks.

Under the Medicare prescription drug benefit, pharmacies must contract with a potential Part D plan in order for their pharmacies to be included in the plan's network of pharmacies. Without such a contract, pharmacies will not be reimbursed for drug purchases made through the plan.

However, some 340B pharmacies have complained that the contracts they have received from potential Part D plans would make it difficult for them to participate.

"We have heard from some health centers that have pharmacies that not all PDPs are necessarily fully apprised of the difference between safety net pharmacies and retail pharmacies and we are hoping that this sample language will give [safety net providers] a better starting point on negotiating contracts so that they can be part of their networks," Hines said.

This issue is critical for 340B and other safety net providers because it is likely that the patients of these entities will be enrollees in a number of different plans. As a result, it

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340B Prime Vendor Signs Contracts with Brand Name Manufacturers

The 340B prime vendor program has announced contracts with two major brand name manufacturers that will extend subceiling discounts to the program's participants on insulin and other products and offer significant discounts on vaccines.

These contracts are among the first cases in which brand name pharmaceutical firms have been willing to contract with the prime vendor program, which was established by the federal government to perform three functions: (1) negotiate subceiling prices for covered entities, (2) establish distribution solutions to improve access to pharmaceuticals, and (3) provide value-added services to its members.

The new contracts with Novo Nordisk and GlaxoSmithKline are the first brand name contracts reached by the prime vendor since signing a deal last year with First Horizon Pharmaceuticals to provide subceiling discounts on the calcium channel blocker Sular.

"I think we're knocking a barrier down," says prime vendor program Senior Director Chris Hatwig of the latest contracts. "They've been the result of a lot of hard work and persistence."

The first of the new contracts, reached with the Denmark-based manufacturer Novo Nordisk, will give prime vendor program enrollees access to subceiling prices on various drugs and products used in diabetes care.

In particular, the contract establishes subceiling pricing on rapid acting insulin, human insulin, and mix insulin, as well as disposable needles and tablets of repaglinide, an anti-diabetic medication that helps lower patients' blood sugar.

New Prime Vendor Program Contracts

Novo Nordisk (subceiling discounts)	**GlaxoSmithKline** (value added service)
rapid acting insulin, human insulin, and mix insulin, as well as disposable needles and repaglinide tablets	discounted pricing on the company's entire line of vaccines.

According to Hatwig, this contract allows Novo Nordisk to renew its commitment to the safety-net community while also potentially improving their market share with respect to analog insulin.

"They're doing the right things for all the right reasons," says Hatwig, citing the fact that Novo Nordisk agreed to offer discounted pricing on human insulin despite the fact that they already offer the best pricing on the market for these products.

"Joining efforts with [the prime vendor program] furthers our commitment to social responsibility by addressing the needs of communities that are underserved and disproportionately affected by diabetes," said Novo Nordisk President Martin Soeters in a press release.

Yet despite the program's success with this contract, Hatwig stops short of predicting that it will lead to a flurry of new brand name contracts, stressing that every company has its own "footprint" and must be dealt with individually.

Nonetheless, he says that other companies have approached the prime vendor program since learning of the Novo Nordisk contract.

Also entering into a recent contract with the prime vendor program was the British company GlaxoSmithKline (GSK), which agreed on March 15, 2005 to a three-year deal that locks in discounts on the company's entire line of vaccines.

Though vaccines are not covered by the 340B program, discounts on GSK's products will be offered to prime vendor program participants as a value-added service, says Hatwig.

"GSK saw the prime vendor pro-

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The Monitor

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The *Federal Drug Discount and Compliance Monitor* is a national monthly newsletter that covers the legal and political issues surrounding the Public Health Service 340B drug discount program and other developments in federal drug pricing law and policy. *The Monitor* also updates subscribers on breaking news stories through e-mail alerts.

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CBO Evaluates Possible Increase to Medicaid Drug Rebate Percentage

A new report released by the Congressional Budget Office (CBO) projects that the federal government could reduce its drug spending by up to $8.3 billion over ten years by increasing the Medicaid rebate percentage on brand name drugs from 15.1% to 20% off of Average Manufacturer Price (AMP), a measure that could also have a significant impact on the 340B ceiling price of these drugs.

According to the agency's February *Budget Options* report, such a change would effectively increase the average Medicaid rebate to 23% off of AMP after taking into account both the increased rebate percentage and the effect that best price has on reimbursement. As a result, mandatory federal spending would decrease by $0.6 billion in 2006 and by $8.3 billion through 2015.

Projected Savings from Increasing the Medicaid Rebate %
(in billions)

2006	2007	2008	2009	2010	2006-2010	2006-2015
$0.6	$.56	$.60	$0.67	$0.75	$3.22	$8.32

Source: Congressional Budget Office

The Medicaid drug rebate formula currently stipulates that Medicaid is entitled to a reimbursement amount of either 15.1% off of AMP or the difference between AMP and the best price available in the private market. This formula is also used to determine the 340B ceiling prices of brand name drugs.

Though the report does not specifically discuss the impact of this proposal on the 340B program, it is likely that—unless otherwise stated—increasing the rebate percentage would mean that 340B entities would then be entitled to a new ceiling price that is based on a figure of AMP - 20% or the best price in the private market for their brand name drugs.

CBO's analysis of this measure comes at a time when the federal government is expecting Medicaid drug spending to decrease due to the introduction of the new Medicare prescription drug benefit, under which all seniors who are eligible for both Medicare and Medicaid will begin receiving their drug coverage through Medicare beginning on January 1, 2006. (For more on "dual eligibles," see *The Monitor*, February 2005).

Nonetheless, the CBO report predicts that Medicaid will continue to see its costs increase from year to year unless appropriate measures are taken. In fact, the report states that federal spending on Medicaid has increased by an average of more than 10% per year since 1999.

"The lower level of spending will still be subject to upward pressures similar to those affecting overall prescription drug spending, which is projected to continue to grow, albeit more slowly than in recent years," the report states.

As an additional benefit, CBO predicts that increasing the rebate percentage to 20% could create an incentive for manufacturers to lower their prices in the private market.

"While many manufacturers offer large discounts to private purchasers, the best price provision can make it relatively difficult for them to offer discounts beyond the flat rebate because any such discount is automatically made available to Medicaid as well," the report states.

As a result, the report argues, increasing the flat rebate would create more room for negotiated discounts that do not trigger the best price provision and could lend more leverage to large purchasers such as health maintenance organizations (HMO) and large hospital systems.

"Thus, some purchasers who now receive a discount at or near the current flat rebate for a particular drug might see a benefit," the report concludes.

However, the report also argues that increasing the rebates paid by manufacturers could potentially lead to reduced revenues for pharmaceutical firms and discourage these companies from increasing their spending on research and development.

"In particular, a policy that reduced Medicaid payments for prescription drugs might discourage the development of new drugs in certain drug classes whose use is heavily concentrated in the Medicaid population," the report states.

The measure analyzed by CBO is an alternative to the plan introduced by President Bush in his 2006 budget proposals. Under the President's proposal, the best price component would be removed from the Medicaid drug rebate formula and replaced with a larger, budget-neutral flat rebate (*The Monitor*, February 2005).

According to the Administration, this measure would allow manufacturers to offer deeper discounts to private purchasers because they would not have to offer those same prices to the Medicaid and 340B programs. Meanwhile, state Medicaid agencies and 340B entities would theoretically not experience any impact because the new flat rebate would be adjusted to ensure that these groups continue to receive the discounts to which they are accustomed.

Opponents of the President's proposal argue that it would be difficult to determine a budget-neutral rebate percentage and that Medicaid and safety-net providers that treat the country's most vulnerable populations should be entitled to the best price in the market.

New York Legislature Closes "Medicaid Carve-Out" Option

The New York State Legislature has passed a law that will require 340B entities to bill Medicaid for covered outpatient drugs at the cost at which they purchased the drug plus a dispensing fee, effectively closing the Medicaid "carve-out option" in the state.

This provision, included among a number of amendments to various bills relating to the state's budget, was passed in both houses of the legislature and signed by Governor George Pataki (R) on April 14.

As a result of this law, 340B pharmacies will no longer have the option of purchasing their Medicaid drugs outside of the 340B program and billing Medicaid at the state's customary rates, a practice known in the 340B community as the "Medicaid carve-out."

Without this option, covered entities in New York will now be forced to purchase all of their covered outpatient drugs through the 340B program and bill Medicaid at a rate based on the cost at which they purchase these drugs.

However, the law also states that covered entities will be entitled to a payment from Medicaid for "reasonable administrative costs," commonly known as a "dispensing fee," at a rate that is to be determined by the Commissioner of the New York State Health Department.

The level at which the dispensing fee is set is likely to determine the impact of the law on 340B entities, says Patricia J. Wang, Senior Vice President of Finance and Managed Care for the Greater New York Hospital Association (GNYHA), a hospital trade association that represents more than 250 non-profit providers in the New York area.

"That's the $64,000 question," says Wang. "How will the Commissioner go about calculating the fee?"

Wang says that she is encouraged by the new law's explanation of a dispensing fee—which takes into account the purchase, dispensing, and tracking of these drugs—though she worries that an insufficient administrative fee could have a negative impact on dispensing pharmacies and could eliminate the incentive for contract pharmacies to dispense drugs for non-profit hospitals.

This bill could translate into significant savings for the state depending on the size of the dispensing fee paid to covered entities.

Though the law states that this measure is to be implemented upon its passage, Wang suspects that the state will have to wait until the Commissioner has determined the dispensing fee before requiring 340B entities to alter their billing practices.

Depending on the size of the dispensing fee, this law could translate into significant savings for the state, seeing as how the 340B acquisition cost of a drug is typically 19% lower than Medicaid net rebate prices, according to a 2001 Prime Institute Study.

340B provider groups have argued that forcing 340B entities to bill at acquisition cost is counterproductive because many 340B entities would likely withdraw from the program rather than change their billing procedures.

"340B providers are already absorbing a loss on their large uninsured population and this loss is compounded when providers are forced to bill Medicaid at acquisition cost," says Bill von Oehsen, General Counsel to the Public Hospital Pharmacy Coalition (PHPC).

State Medicaid agencies, on the other hand, have contended that these entities should not be permitted to bill the state at an amount that exceeds the cost of the drug being dispensed.

One solution for New York, says von Oehsen, is what he refers to as an "enhanced dispensing fee" model. Under this approach, entities are required to bill Medicaid at acquisition cost, though they are compensated with a dispensing fee that allows the covered entity to maintain a portion of the savings they receive through their 340B discounts.

This model is designed to allow states to save a significant amount of the difference between a drug's typical Medicaid reimbursement amount and its 340B acquisition cost.

Prime Vendor Contracts With Brand Name Manufacturers

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gram as an efficient way of distributing their vaccines," says Hatwig. "Such access is critically important to patients, and we're pleased to partner with GlaxoSmithKline to make some of their key products available to these patients."

Hatwig is hopeful that the GSK contract, which took nearly a year to negotiate, will open the door to other contracts between the company's other divisions and the prime vendor program.

With respect to value-added services, Hatwig says that the prime vendor program is dedicated to offering "one stop shopping" for its participants in order to provide more comprehensive members services

"Companies that provide these services recognize the value of this program," he says, adding that the program looks to contract for "any product that grantees might need, providing there is enough demand."

For instance, the prime vendor program is currently in discussions with manufacturers of prescription viles, syringes, and other products that might be of interest to the program's community health center participants.

The prime vendor currently has 1,090 participants enrolled, including 444 disproportionate share hospital sites, 234 community health center sites, and nearly 200 family planning clinics.

Congressional Budget Resolution Calls for $10 Billion in Medicaid Cuts

After weeks of debate, Congress narrowly passed a budget resolution on April 28 that includes a call for $10 billion in Medicaid savings over the next five years and could result in significant changes to the Medicaid pharmacy reimbursement system.

The $10 billion savings figure is significantly less than what the President requested in 2006 budget proposal and half of what was originally approved by the House of Representatives.

As part of a compromise reached in the Senate, the resolution does not require that Congress make cuts to Medicaid until fiscal year 2007 and calls for the creation of a Medicaid Commission to review the program.

Despite opposition from Senate Democrats who favored an independent commission, recent press reports indicate that Health and Human Services Secretary Michael Leavitt will select all of the commission's voting members.

One area that is likely to be targeted by the commission, as well as by the House Energy and Commerce Committee and the Senate Finance Committee as they consider cuts, is Medicaid pharmacy reimbursement. Proposals that call for a move away from an Average Wholesale Price (AWP) system have garnered bipartisan support in recent months.

One particularly active member of Congress with respect to this issue has been House Energy and Commerce Committee Chairman Joe Barton (R-TX), who convened a hearing on Medicaid pharmacy reimbursement at the end of last year. Barton said then that he plans to address this issue by the end of the year (*The Monitor*, December 2004).

It is unclear what kind of system Barton will endorse to replace the current AWP method of reimbursement, though it appears that he has not yet found one to his satisfaction. During a May 3 speech delivered at a meeting of the National Community Pharmacists Association (NCPA), Barton addressed the Medicaid reimbursement debate and told the audience that the AWP system must be abandoned.

However, according to press accounts of the speech, Barton also said that he is not interested in replacing the current system with a methodology based on Average Sales Price (ASP), which is currently being used to reimburse drugs under Medicare Part B and was included in the President's Medicaid budget proposal.

Barton told conference attendees that his committee plans to look more closely at this issue this summer as his committee begins its efforts to come up with $2 billion in Medicaid savings per year for the next five years.

Meanwhile, the prospects for the Bush Administration proposal to eliminate the best price system used to determine Medicaid and 340B discounts appear less certain.

The President had suggested in his budget proposal that Congress reform the Medicaid drug rebate program by eliminating best price from the rebate formula and replacing it with a larger, budget-neutral rebate percentage in order to encourage manufacturers to lower their prices in the private market (*The Monitor*, February 2005).

A number of state governors, state Medicaid directors, and 340B providers have expressed significant concerns over the Administration's "best price" proposal. As an alternative, the National Governors Association (NGA), which has been working with the President on reforming Medicaid, has proposed that the government increase the rebates that manufacturers are required to offer to Medicaid while maintaining the best price mechanism.

Other measures that are likely to be considered by Congress in their efforts to identify Medicaid savings include restrictions on asset transfers and intergovernmental transfers (IGTs) as well as modifications to provider taxes and administrative claiming.

The two committees are directed to submit their budget cut proposals by September 15.

Report Examines Coverage Gaps in Medicare Rx Benefit

Seniors with chronic conditions who enroll in the new Medicare prescription drug benefit will see only modest decreases in drug spending and may actually choose to decrease their medication use due to the large coverage gaps included in the program, according to a study conducted by researchers at the University of Maryland.

The study, recently published in the journal *Health Affairs*, concludes that "Medicare beneficiaries react to interruptions in prescription coverage by reducing their drug spending and that the impact is magnified for beneficiaries with three common chronic diseases," i.e. diabetes, lung disease, and mental illness.

Under the new prescription drug benefit, which will go into effect on January 1, 2006, standard beneficiaries will be required to pay a deductible of approximately $250 before Medicare coverage kicks in. The program's design also includes a range of spending during which beneficiaries will be responsible for covering all of their drug costs—known as the "doughnut hole."

More generous benefits are available to low-income beneficiaries (For more details on the Medicare Part D prescription drug benefit, see *The Monitor*, December 2004).

According to the study, seniors who are treated for diseases such as diabetes or lung disease are likely to reach the "doughnut hole" faster than the average beneficiary due to their higher drug costs, which translates into a longer period of time during which these patients are paying for the full cost of their drugs out-of-pocket.

As a result, the authors of the study argue that some beneficiaries who are accustomed to continuous coverage may react to coverage gaps—as well as the increased costs that they incur during these gaps—by choosing to limit the amount of their medications that they purchase.

The report estimates that average beneficiaries are likely to spend slightly more than two months in a coverage gap—split equally between the time they spend paying down their deductible and the time they spend in the "doughnut hole"—while their out-of-pocket spending will drop by 55% once the program begins in 2006.

By contrast, beneficiaries with chronic conditions will spend a longer period of time without coverage—up to four months—due to their higher drug costs. Therefore, beneficiaries with chronic lung disease and mental illness will see decreases in their out-of-pocket spending of only 19% and 16%, respectively.

"Of course, not all beneficiaries are average, and most of those with above-average spending will experience even longer benefit gaps before the generous catastrophic coverage finally kicks in," the report states.

> ***"Most of those with above-average spending will experience even longer benefit gaps before the generous catastrophic coverage finally kicks in."***
>
> **Bruce Stuart, et. al**
> **University of Maryland**

The report also points out that, due to the benefit's design, these outcomes could be compounded by the fact that beneficiaries will be exposed to the same coverage gaps each year that they are enrolled in the program.

To conduct the study, the authors examined the ways in which Medicare beneficiaries reacted to gaps in their private drug coverage from 1998-2000. This analysis revealed that beneficiaries tended to reduce their drug spending by more than $25 with each month that passed while they did not have prescription drug coverage.

During that time, drug spending for beneficiaries with chronic conditions was anywhere from $1,666 - $2,282 more than average beneficiaries, depending on the disease.

Based on these figures, the authors of the study were able to simulate the effect of coverage gaps on beneficiaries in the new Medicare drug benefit.

According to press reports, Centers for Medicare and Medicaid Services (CMS) Administrator Mark McClellan has responded to the study saying that "beneficiaries with chronic illnesses are going to save more money as a result of this drug coverage" and that low-income beneficiaries will not be charged deductibles or premiums and will be responsible for only "a few dollars" in copayments.

Though the study focused primarily on diabetes, lung disease, and mental illness, the authors say that there is reason to believe that "a similar fate may be in store for beneficiaries with other chronic illnesses."

The Maryland study appears to be supported by another report related to the Medicare prescription drug benefit published by researchers from Brandeis University, which explores the reasons why various groups of seniors—including those without drug coverage, those with low incomes, and those with complex chronic conditions—choose not to adhere to the drug regimens recommended by their physicians.

According to the study, 52% of seniors with complex chronic conditions say that they have chosen not to adhere to their drug regimen for various reasons, as opposed to 40% of the total senior population.

More specifically, 35% of seniors with complex chronic conditions report that they have foregone their medications on at least one occasion due to the cost of their drugs, as opposed to 26% of all seniors.

"The complex chronically ill were at highest risk for all three types of nonadherence, which reflects their reliance on multimedication, costly regimens," the report concludes.

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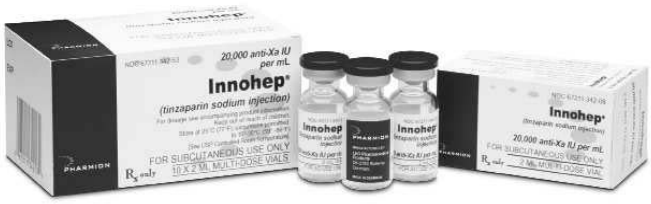

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CMS Narrows Best Price and AMP Exemptions for SPAPs

Pharmaceutical sales made to state-funded pharmacy assistance programs (SPAP) that direct their members to a preferred plan under the new Medicare prescription drug benefit will not be exempted from best price and Average Manufacturer Price (AMP) reporting to the Medicaid program, according to a release issued by the Centers for Medicare and Medicaid Services (CMS) on April 1.

CMS Medicaid Drug Rebate Program Release #68, which is directed to drug manufacturers, expands the criteria that state-operated pharmacy programs must meet in order to qualify as SPAPs and receive an exemption from best price and AMP reporting, and says that state programs that steer beneficiaries to a particular plan will be regarded as violating the "non-discrimination" provision of the Medicare Part D statute.

SPAPs are state-administered programs that provide pharmaceutical benefits to disabled, indigent, low-income elderly, or other financially vulnerable individuals. These programs rely on state, local, and private funding rather than federal funding, and usually obtain discounts or rebates on drugs either through negotiations with drug companies or in accordance with state law. There are currently 21 states with SPAP programs in place, according to CMS figures.

The new CMS release is a revision of two prior releases that describe which programs qualify as SPAPs for the purpose of granting best price and AMP exemptions. According to the most recent of the two (#59), a qualifying program must meet five criteria: (1) it must be developed specifically for "financially vulnerable persons," (2) it must be funded entirely by the state, (3) it must be structured such that payment is provided directly to providers, (4) it must provide a pharmaceutical benefit, and (5) it must not allow for the diversion or transfer of benefits to non-beneficiaries.

The releases also specifically state that programs that "reflect traditional state responsibilities"—such as medical programs for prison inmates—do not qualify for an exemption.

Release #68 adds an additional element to the SPAP definition which requires that the program abide by the "non-discrimination" provision of the Medicare Part D statute—which CMS has interpreted to prohibit SPAPs from steering beneficiaries to a particular plan in any way.

According to the release, CMS was prompted to modify its definition of an SPAP after learning about a model that a number of states were developing in connection with the new Medicare drug benefit.

Under this model, a state program would facilitate direct enrollment of its beneficiaries into specific drug plans by acting as a representative for its members in the enrollment process. This model would also allow states to collect rebates on the drugs purchased for their members, which could in turn be used to offer additional assistance to Medicare-covered SPAP beneficiaries.

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FTC Decisions Allow Non-Profit Hospitals to Resell Discounted Drugs

The Federal Trade Commission (FTC) has widened its interpretation of the "own use" standard to allow hospitals to resell or otherwise transfer their discounted drugs to other non-profit organizations and to offer these drugs to all patients receiving care from the hospital or its clinics even if the prescriptions are written by non-hospital physicians, which may create new opportunities for both 340B hospitals and non-profits in search of discounted pharmaceuticals.

In an April 18 letter to Stevens Hospital—located in Edmonds, WA—the FTC's Acting Administrator of the Bureau of Competition argued that allowing the hospital to sell its discounted drugs to patients of hospital-owned clinics and to patients referred by hospital staff to non-hospital specialists is consistent with the "own use" provision of the Non-Profit Institutions Act (NPIA).

According to the NPIA, non-profit organizations are given an exemption from the Robinson-Patman Act such that they are allowed to receive preferential pricing as long as the goods they purchase are for their "own use."

In the case of Stevens Hospital, the FTC decided that clinics owned by the hospital are components of the hospital's mission to provide comprehensive care to its patients and that any internal sales made to these clinics' patients would meet the "own use" standard.

Most notably, the letter also states that hospitals may transfer their discounted drugs to any patients who receive ongoing treatment from the hospital, including those who are referred to a specialist. As a result, hospitals may be permitted to fill non-hospital prescriptions with discounted drugs.

The Stevens opinion comes one year after the FTC ruled that Dunlap Memorial Hospital—located in Orrville, OH—was permitted to transfer its discounted drugs to any other entity that is also exempt under the NPIA. The Dunlap decision also stated that hospitals may charge an administrative fee to the entity that receives the drugs to cover the costs of handling the drugs.

It is unclear whether this opportunity applies to 340B hospitals because distribution of 340B-discounted drugs is governed under the 340B definition of "patient" rather than by the NPIA "own use" standard.

However, the two decisions may create an opportunity for 340B hospitals to provide clinics and other non-profits with discounted drugs for individuals who fall outside the 340B patient definition guidelines but within the "own use" standard.

CMS and HRSA Address Pharmacy Networks, Co-Branding

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will be necessary for these institutions to enter into contracts with a number of PDPs to ensure that they will be reimbursed through Medicare.

Another issue facing 340B pharmacies is that many will not be able to serve all of the enrollees in various Part D plans because these pharmacies are only permitted to dispense 340B drugs to their own patients.

Provider groups, including the Public Hospital Pharmacy Coalition (PHPC) and other 340B entity groups, have been active in encouraging CMS and HRSA to ensure that 340B pharmacies are not excluded from PDP pharmacy networks during the contracting process.

To accommodate these entities, Hines said that CMS has updated an online form that currently allows all interested pharmacies to post their contact information for potential PDPs. On the new form, pharmacies can now identify themselves as 340B providers.

To ensure that their pharmacies are able to receive reimbursement through Medicare, CMS's Richard Lawlor suggested to a caller that safety net providers "offer yourselves to as many PDPs as possible." CMS also stressed that these contracts must be reached soon in order for pharmacies to begin receiving reimbursement immediately after the benefit is launched.

Another issue addressed during the Open Door Forum was the idea of "co-branding" arrangements between 340B entities and potential PDPs that would allow a covered entity to partner with a PDP to facilitate enrollment into an entity-specific plan so that the entity's patients can be served in its pharmacy.

According to PHPC General Counsel Bill von Oehsen, who attended the forum, there are currently eight such arrangements under the Medicare drug discount card program, which will give way to the new drug benefit in January.

Von Oehsen argued that this arrangement would be ideal for 340B entities because he believes their patients "are much more likely to affirmatively sign up for a drug plan knowing that their provider has their name and logo on the card."

CMS and HRSA officials stated that they have not yet formulated a policy on this kind of arrangement, though HRSA's Alex Ross said that they would encourage safety net providers and PDPs to work together in co-marketing the drug benefit to their patients.

CMS Release Challenges State Pharmacy Assistance Programs

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For example, some states planned to use these rebates to cover the copayments required of low-income patients or to provide assistance in paying for drugs that are excluded from Medicare drug plan formularies.

Under the new CMS guidance, manufacturers who sell pharmaceuticals to SPAP programs that violate the Medicare "non-discrimination" provision will now have to include these prices in their best price and AMP calculations under the Medicaid drug rebate law. Therefore, manufacturers would have a strong disincentive to offer significant discounts to such SPAPs because the prices they offer would in turn lower prices in the Medicaid and 340B programs.

In a memorandum issued to potential program sponsors, state Medicaid directors, and SPAPs, CMS Deputy Administrator Leslie Norwalk asserted that non-compliant SPAPs "eliminate choice for the low-income subsidy population" by directing them to a particular plan.

According to the memo, these programs could also potentially lead to higher drug costs for beneficiaries because the rebates would be directed to the states rather than to drug plans that could in turn lower prices for their low-income enrollees.

Norwalk also said that this type of non-compliance by SPAPs could potentially constitute fraud or abuse because "the State receives a financial benefit even though it incurs little to no financial burden, while the Federal government and Medicare beneficiaries do not receive the benefit."

Opponents of the release, on the other hand, have characterized it as a heavy-handed and unlawful attempt by CMS to use punitive measures under the Medicaid program as a means of enforcing legally questionable provisions of the new Medicare regulations.

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