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Medicaid and the 340B Program: Alignment and Modernization Opportunities

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Executive Summary

This Issue Brief is part of NAMD's ongoing work to offer constructive solutions to identified challenges states experience in seeking to design and administer high-value programs. This publication addresses the need to ensure states are able to meet the full scope of responsibilities for program management and oversight of the Medicaid program when these duties overlap or intersect with the 340B program.

Both the Medicaid program and the 340B program play an important role in the provision of pharmaceuticals to individuals in need. In many ways, the programs are complementary to each other. Unfortunately, the complexity at the intersection of the two programs has created administrative burden and compliance concerns for state Medicaid programs.

Brief Background

The 340B program requires pharmaceutical manufacturers participating in the Medicaid or Medicare Part B programs to enter into a pharmaceutical pricing agreement (PPA) with the Secretary of the U.S. Department of Health and Human Services (HHS). The terms of the PPA require manufacturers to provide discounts on covered outpatient drugs purchased by specified safety net providers, known as covered entities (CEs). Federal statute provides that manufacturers are not required to provide a discounted 340B price *and* a Medicaid drug rebate for the same drug – in other words it prohibits "duplicate discounts."

Purchases under the 340B drug discount program are estimated to have grown from $0.8 billion in 2004 to $7.2 billion in 2013.[1] The number of covered entity sites participating in the 340B program has grown from over 8,600 in 2001 to nearly 16,600 in 2011. From 2005-2011, the number of hospitals participating nearly tripled, from almost 600 to over 1,600, and the number of hospital sites (separate locations of a given hospital that all participate in 340B) almost quadrupled, from 1,233 to 4,426.[2] Between March 2010 and May 2013, the percentage of all covered entities that use contract pharmacies has risen from 10 percent to 22 percent. The number of unique pharmacies serving as 340B contract pharmacies has grown by 770 percent, and the total number of contract pharmacy arrangements has grown by 1,245 percent.[3]

As more covered entities and more contract pharmacies enter the 340B landscape, the challenges for state Medicaid programs grow larger in scope.

The 340B Program: Challenges for State Medicaid Programs

The 340B program's growth and expansion to new types of CEs has led to a corresponding increase in workload for state Medicaid programs. The evolution of the 340B program also is

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[1] Drug Channels blog, February 25, 2014: http://www.drugchannels.net/2014/02/exclusive-340b-is-taking-over-hospital.html

[2] Government Accountability Office, Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement, GAO (Washington, D.C.: Sep. 2011)

[3] HHS Office of Inspector General Memorandum Report: "Contract Pharmacy Arrangements in the 340B Program", February 2014: http://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf

creating pressure to develop policy and operational processes to accommodate new business opportunities related to 340B discounts. However, federal policy guidance and capacity has not kept pace with these changes. This puts states at ever greater risk for non-compliance with federal rules. Further, the burden on state Medicaid agencies to manage interactions with the 340B program is increasingly difficult to manage without incurring additional operational costs.

This paper addresses the following issues:

1. The Medicaid Exclusion File
2. Patient Identification Challenges
3. Provider Procurement Issues
4. Dispute Resolution Issues
5. Complexities in Medicaid Managed Care Programs
6. Complexities with Contract Pharmacies
7. Transparency of Pricing
8. "Shared Savings" Models
9. Claims Reimbursement for Outpatient Hospital Administered Drugs

NAMD Goals

With the continued growth of Medicaid and the 340B program comes a need for alignment of requirements and communication between and across the federal and state governments. The Center for Medicare and Medicaid Services (CMS) and the Health Resources and Services Administration (HRSA) must work together to provide states the guidance, tools, and transparency to ensure that the two programs can complement each other to serve those most in need of pharmacy services. Such updates may require enhanced capacity within HRSA's Office of Pharmacy Affairs to improve and properly staff the federal functions relevant to the 340B program. Additionally, many of the process improvements and technical changes that would be helpful will require collaboration with states to fully develop.

Proposed Solutions

Targeted solutions could help strengthen compliance and streamline processes for Medicaid programs and CEs. Listed below is a high level summary of changes states wish to pursue with the federal partners, with additional detail contained in the full brief.

Effectuate technical enhancements to the Medicaid Exclusion File. Today, there are many obstacles preventing CEs and states from easily separating and identifying claims to prevent "duplicate discounts." The following changes would help prevent duplicate discounts and allow for earlier identification of violations that do occur.

- Develop a solution for providers serving patients in multiple states.
- Implement HRSA-level editing against the National Provider Identifier (NPI) number.
- Publish a quarterly change file that reflects HRSA-validated changes in CE status.

- Clarify the effective date of a provider's status on the 340B exclusion list, including "carve-in" and "carve-out" dates.[4]
- Update the Pharmaceutical Pricing Agreement to require drug manufacturers to identify "duplicate discount" issues within one year, but no more than 3 years.
- Limit retroactive changes to the exclusion file in order to reduce complications to the Medicaid drug rebate process.
- Provide guidance to states that addresses situations where CEs do retroactively change their status.
- Require drug manufacturers to work with CEs to prevent the "duplicate discount."
- Establish mechanisms to improve communication between CEs and Medicaid agencies.

Facilitate Claims-Level Identification of 340B-Procured Prescriptions. Gaps and disconnects in operational standards can impede more efficient operation of state Medicaid programs as well as operations for the federal partners, CEs and manufacturers. HRSA and CMS can begin to address these issues in the following ways.

- Promote effective practices for coding issues, with a specific focus on systematic solutions rather than manual processes.
- Ensure there is a mechanism to facilitate identification of specific CE claims within contract pharmacy arrangements.
- Require Medicaid managed care entities and their Pharmacy Benefit Managers (PBMs) to use unique identifiers to distinguish their 340B Medicaid claims from their 340B commercial or Medicare Part D business.

Issue Clear Guidance and Strengthen Enforcement Practices. There is insufficient information about federal expectations for reporting and classification of 340B claims in a Medicaid managed care model. The federal agencies should provide clear, coordinated guidance for states, managed care entities, and 340B covered entities. The following actions could help clarify expectations.

- Clarify treatment of Medicaid fee-for-service (FFS) and managed care-based claims within the Medicaid Exclusion File so that states can identify CEs which differ their 340B "carve-in" status based on the delivery system model.
- Conduct timely audits of CEs and enforce requirements that CEs work with state Medicaid agencies and HRSA to properly identify and exclude claims from contract pharmacies.

Improve Transparency Related to Reimbursement and Clearly Articulate Expectations. The lack of pricing transparency for 340B claims can make it difficult for states to design appropriate payment policies and ensure that existing policies are being adhered to by CEs. Additional pricing transparency can also assist states in maximizing the efficacy and value of the 340B program. Steps to address this include the following:

[4] HRSA directs CEs to determine whether they will use 340B drugs for their Medicaid patients (carve-in) or whether they will purchase drugs for their Medicaid patients through other mechanisms (carve-out). See: http://www.hrsa.gov/opa/programrequirements/medicaidexclusion/index.html

- Explore the development of a 340B benchmark, such as “average 340B acquisition price,” that could be shared with the states.
- Collaborate with states to develop guidance related to “shared savings” arrangements with 340B entities.

Medicaid and the 340B Program: Alignment and Modernization Opportunities

340B: Brief History and Background

The 340B program was created under the Veterans Health Care Act of 1992. The program's stated intent is to permit eligible safety net entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[5] Benefits of participation in the 340B program include, but are not limited to:

- A reduced price of pharmaceuticals for patients,
- The ability to expand services offered to patients, or,
- An option to provide services to more patients.[6]

The program is operated by the U.S. Department of Health and Human Services, Office of Pharmacy Affairs of the Health Resources and Services Administration (OPA/HRSA). The HRSA website and associated rules and guidance provide a definition of a patient who may be dispensed the discounted drugs. The site also defines the Covered Entities (CEs), the providers who are eligible to purchase drugs at the 340B discounted price. CEs that may participate in the 340B program are defined in federal statute and regulation and include facilities such as disproportionate share hospitals, certain children's hospitals, rural referral centers, black lung clinics, and many other types of providers who serve traditionally underserved populations. The Affordable Care Act (ACA) expanded the definition of a CE to include critical access hospitals, free-standing cancer hospitals, sole community hospitals and rural referral centers. Drug manufacturers are required to participate in the 340B program as a condition of their products being covered by the Medicaid program.[7]

During the past decade, purchases under the 340B drug discount program are estimated to have grown from $0.8 billion in 2004 to $7.2 billion in 2013.[8] The number of covered entity sites participating in the 340B program has grown from over 8,600 in 2001 to nearly 16,600 in 2011. From 2005-2011, the number of hospitals participating nearly tripled, from almost 600 to over 1,600, and the number of hospital sites (separate locations of a given hospital that all participate in 340B) almost quadrupled, from 1,233 to 4,426.[9] Between March 2010 and May 2013, the percentage of all covered entities that use contract pharmacies has risen from 10 percent to 22

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[5] H.R. Rep. No. 102-384(II), at 12 (1992)

[6] HRSA Pharmacy Services Support Center: The 340B Access Resource, webinar slides: http://www.hhs.gov/opa/pdfs/340b-prime-vendor-programs-slides.pdf

[7] See: http://www.hrsa.gov/opa/manufacturers/

[8] See: http://www.drugchannels.net/2014/02/exclusive-340b-is-taking-over-hospital.html (February 25, 2014)

[9] Government Accountability Office, Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement, Sept. 2011

percent. The number of unique pharmacies serving as 340B contract pharmacies has grown by 770 percent, and the total number of contract pharmacy arrangements has grown by 1,245 percent.[10]

The 340B Program's Intersection with Medicaid

There are a number of issues that occur in the 340B program which affect the Medicaid program and CEs in ways that may not have been anticipated at the program's inception. These must now be addressed to ensure that all stakeholders – states, CEs, managed care entities, manufacturers and contracted pharmacies – can work together to ensure the program is operating as intended. As more CEs and contract pharmacies enter the 340B marketplace, the challenges for Medicaid programs grow larger in scope. Collaboration and guidance at the federal level is needed to address these mounting challenges.

340B and Medicaid Issues

The primary issue at the intersection of Medicaid and 340B is the requirement that Medicaid programs, drug manufacturers, and 340B entities avoid duplicate discounts, also known as "double dipping." Duplicate discounts occur when a Medicaid program invoices a manufacturer for the federal drug rebate for prescriptions which have been purchased at the 340B rate by a CE.

HRSA's guidance states that the CE and drug manufacturers hold the primary responsibility to avoid duplicate discounts. [11] The CE must notify HRSA of its intent to use 340B products for Medicaid patients and place itself on the Medicaid Exclusion File, which is published quarterly by HRSA. This option is known as "carving in" the Medicaid program.[12]

Individual Medicaid programs then have the responsibility to both identify the 340B providers and to exclude the CE's claims from Medicaid rebate billing. Individual states may have additional notification requirements for entities choosing to carve in. HRSA is also clear in its enrollment requirements that:

> "If covered entities decide to bill to Medicaid for drugs purchased under 340B with a Medicaid provider number/NPI, then ALL drugs billed to that number must be purchased under 340B and that Medicaid provider number/NPI must be listed on the HRSA Medicaid Exclusion File." [13]

HRSA's guidance essentially requires CEs to take an "all or nothing" approach to Medicaid patients and 340B products. While identifying 340B claims and exempting them from state rebate billing processes sounds like a simple proposition, the reality of operationalizing these processes is complex.

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[10] HHS Office of Inspector General Memorandum Report: "Contract Pharmacy Arrangements in the 340B Program", February 2014: http://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf

[11] See: http://www.hrsa.gov/opa/programrequirements/medicaidexclusion/index.html

[12] Ibid.

[13] Ibid.

Duplicate discounts are a risk due to operational issues and lack of alignment between policy guidance to states and operational guidance to CEs. Further, rapidly evolving market opportunities has contributed to the challenges.

Issue 1: The Medicaid Exclusion File

HRSA's "all or nothing approach" framework requires CEs to bill the Medicaid program under a specific provider identification number. The provider identification number must be listed on the Medicaid Exclusion File and must be used for all drugs billed by that provider identification number (NPI). However, there are situations where this requirement is not operationally feasible. For example, HRSA currently does not address how an entity that carves-in Medicaid should report exceptions to using 340B drugs – a scenario which can and does happen. Modification to the "all or nothing" approach, however, would require thoughtful consultation with states to ensure it does not have unintended consequences or create new challenges.

Out-of-state CEs present another challenge related to the exclusion file. Out-of-state provider NPI numbers are listed under the state where they are doing business. However, these providers may be using 340B stock and billing another state's Medicaid program as a border provider or other entity. It is unreasonable to assume that an out-of-state provider's status on the Medicaid Exclusion File for one state is applicable to another state given the mix of reimbursement models in use by state Medicaid agencies. A CE may decide that 340B reimbursement is acceptable in one state and not in another. Yet, the exclusion file does not allow for a CE to "carve in" for one state but "carve out" for another.

There are also technical issues with the exclusion file itself and its usability. There are significant ramifications to Medicaid rebate billings if a CE fails to list all provider numbers or makes a typographical error when entering NPIs. Since there is currently no HRSA review of the information submitted, significant errors can persist for multiple cycles.

Additionally, a full Medicaid exclusion replacement file is published on the HRSA website quarterly. After each publishing, it is necessary for each state Medicaid agency, or its rebate contractor, to perform a file comparison to determine additions, deletions, or updates to the file. States also struggle with identifying changes in CE carve-in/carve-out dates. Currently HRSA does not make a change file available for states to streamline this work, which results in additional administrative burden and costs for each state.

Issue 2: Patient Identification Challenges

States have observed that the prescription processing operations at some CEs may not be sufficiently robust or flexible enough to adequately identify Medicaid patients. For example, the patient may not be Medicaid eligible on their first visit to the CE, but might have Medicaid eligibility at a subsequent visit. Also, due to retroactive eligibility for Medicaid, a patient's status might change after a prescription has been dispensed.

Additionally, ambiguity still exists with the definition of a "patient," and can lead CEs to incorrectly identify an individual as 340B eligible. This can have a downstream impact on state Medicaid agencies because they are expected to invoice manufacturers for Medicaid rebates for any 340B-ineligible claims.

Issue 3: Provider Procurement Issues

While rare, drugs may not always be available at 340B prices, but the current policy framework and systems make it difficult to manage these situations. There is no mechanism in place for a CE to notify a state Medicaid agency about 340B unavailability. As noted above, this is problematic because states are expected to invoice manufacturers for Medicaid rebates.

Orphan drugs can be similarly challenging for CEs and states to manage. The ACA's orphan drug provision applies the 340B price to the drug only if it is used for its orphan-designated diagnosis within one of the "Newly Covered Entities" (NCEs) -- free-standing cancer hospitals, rural referral centers, sole community hospitals, and critical access hospitals). This is referred to as the orphan drug exclusion. However, many drugs have both orphan and non-orphan indications. NCEs subject to the orphan drug exclusion are responsible for ensuring that any orphan drugs purchased through the 340B program are not transferred, prescribed, sold, or otherwise used for the rare condition or disease for which the orphan drugs are designated under section 526 of the Federal Food, Drug, and Cosmetic Act.

The orphan drug exclusion conflicts with the "all or nothing" requirement for billing 340B drugs to state Medicaid agencies under the excluded Provider Identification Number. NCEs do not have a method to easily identify this situation. Additionally, there is no consistent mechanism in place to differentiate the orphan 340B vs non-340B billings on claims to the state Medicaid agency.

State Medicaid agencies are also aware of instances of manufacturers not extending ***any*** 340B pricing to NCEs on drugs with an orphan indication, regardless of the drugs' use for an orphan or non-orphan indication. States appreciate that HRSA has provided a list of manufactures not offering 340B pricing on their orphan drug products; unfortunately this does not represent a definitive list. As a result, Medicaid programs are challenged to comply with the requirement that they invoice manufacturers for rebates for these products.

Issue 4: Dispute Resolution Issues

HRSA's guidance states that CEs are responsible for resolving duplicate discount issues that may occur. Still, remedying disputes is time and resource consuming for the state Medicaid agency. Specifically, it is typical for the CE to require claims-level detail from the Medicaid agency in order for the CE to resolve the dispute and determine possible repayment. Additionally, disputes are currently permitted many years after the claim was submitted, yet the CE may only retain dispensing records for a limited period of time, as may be required by state law.

Related to disputes, routine HRSA audits can lead CEs to retroactively change their status. Often these changes require states to develop special programming capable of reporting CE claims-level detail for audit period quarters. These changes also put states at risk for rebates owed to manufacturers depending on the date of the retroactive change, which in some cases have gone back as far as five years. Again, the policy and operational actions by CEs may result in additional costs and administrative burdens on states.

Issue 5: Complexities in Medicaid Managed Care Programs

Managed Medicaid claims present an additional challenge for CEs and states in avoiding duplicate discounts. Rebate invoicing for managed care claims was newly required under the ACA.

However, states have not yet received clear guidance regarding the federal agencies' expectations for these claims, including strategies to prevent duplicate discounts, as well as operational issues that arise.[14],[15]

The following issues and dynamics complicate the Medicaid-340B interactions in Medicaid managed care models:

- Currently there is no acceptable mechanism for HRSA, the states and/or the CEs to record the CE's Medicaid carve-in or carve-out status. If a CE uses the same NPI for their Medicaid FFS and managed care entities, it is relatively simple for the Medicaid program to identify 340B claims, provided the CE is making the same decision for FFS as it is for managed care. A decision by the CE to do otherwise, for example carve-out FFS Medicaid but carve-in managed Medicaid, presents challenges for the CE and the state Medicaid agency. In the absence of MCO inclusions in the Medicaid Exclusion File, states have pursued varying approaches to the carve-in versus carve-out status for managed Medicaid Care claims.
- State Medicaid agencies may be blind to the contents or terms of managed care organizations' (MCO) network contracts. MCOs often contract with a Pharmacy Benefit Manager (PBM), who in turn contracts with the pharmacies used by the 340B entities. Some providers have been reluctant to share with a PBM whether or not a prescription was procured via 340B pricing.
- The strategies employed by many managed care entities' with respect to contracting with 340B entities are still maturing.
- Many MCOs have both Medicaid and commercial business. However, CEs are unable to differentiate between the two in the absence of Bank Identification Number and Processor Control Number (BIN/PCN) combinations unique to Medicaid plans.

Issue 6: Complexities with Contract Pharmacies

Contract pharmacies are an arrangement in which the 340B covered entity signs a contract with a pharmacy to provide pharmacy services.[16] Contract pharmacies can add to the complexity of Medicaid and 340B interactions.

States cannot use a simple exclusion list for contract pharmacies, as they generally are Medicaid-enrolled community pharmacies that bill numerous non-340B claims. Since both 340B and non-340B are billed using the same NPI of a contract pharmacy, it is impossible for state Medicaid programs to exclude or include all the claims coming from that NPI for rebate purposes. While it is theoretically possible for a community pharmacy to obtain separate NPIs for their 340B and non-340B business, this is rarely done in practice.

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[14] Section 2501(c) of the ACA required drug manufacturers to pay rebates for covered outpatient drugs reimbursed dispensed by Medicaid managed care organizations (MCOs) for states to receive federal matching funds.

[15] HRSA 340B Drug Pricing Program Notice, December 12, 2014: http://www.hrsa.gov/opa/programrequirements/policyreleases/clarificationmedicaidexclusion.pdf

[16] HRSA Contract Pharmacy Services website: http://www.hrsa.gov/opa/implementation/contract/index.html

Since NPI-level claims exclusion is not feasible for contract pharmacies, another mechanism must be used for Medicaid to identify claims. The contract pharmacies can either identify claims as 340B eligible at the Point of Sale (POS) or retrospectively. However, a contract pharmacy often will not know that a patient is 340B eligible at the time of dispensing. Therefore, retroactive identification of 340B claims is the most common model in practice today.[17]

Retrospectively identified 340B claims pose challenges related to the prevention of duplicate discounts. For example, claims identified retroactively may at times fall outside of states' timely filing limits. In addition, once the claim is identified as 340B eligible, it may be past the time period that large chain pharmacies allow their staff to make changes to a prescription claim record. As a result, the corporate office is required to contact the payer for resource intensive manual reprocessing of the claim or claims.

The claims-level identification of 340B claims also creates challenges in Medicaid managed care programs. For example, the pharmacies may be adding the correct indicators to the claim, but the indicators were not being passed through to the state by the PBM or the managed care entity. Additionally, some contract pharmacies and the CEs they are working with do not use the indicator to identify the claims as 340B. States are aware of proposals to use a retrospective report process between the CEs and the states.[18] However, such a process is prone to error, extremely burdensome to states and could create complexities with auditing and oversight.

The HRSA allowance of multiple contract pharmacies serving a single CE adds an additional layer of complexity to the problem of identifying and preventing duplicate discounts. Without a one-to-one relationship between the contract pharmacy and the CE, it can be difficult to coordinate the policies and procedures of all parties to ensure compliance.

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[17] Many 340B entities contract with 340B administrators, whose role is to identify which claims are 340B eligible after the time of dispensing. In this model, the contract pharmacies use their retail stock to fill the original prescription. The 340B administrator later determines that the prescription eligible to be filled with 340B procured product and the quantity is recorded as a 340B dispensing. Once the contract pharmacy has dispensed an entire package of product attributable to the 340B program, the 340B entity buys and replenishes the pharmacy's stock with 340B purchased drugs. If the prescription was dispensed for a Medicaid enrollee, the contract pharmacy would then need to reprocess the claim as a 340B claim. NCPDP has developed an N1 informational transaction which has been suggested as an option for a pharmacy to retrospectively identify 340B claims for a payer. However, the N1 has not been adopted widely to date and at this time will not work for 340B Medicaid claims, as the transaction does not contain claims payment information and Medicaid Management Information System (MMIS) and POS systems are unable to recognize it.

[18] In a retrospective process the CE would send a detailed report of 340B claims to the state and the state would have to manually exclude these claims from rebate.

Issue 7: Transparency in Pricing

A secondary issue at the intersection of 340B and Medicaid relates to payment and reimbursement for 340B-procured prescriptions. States face operational, financial, and policy challenges in this area.

While HRSA establishes a 340B ceiling price based on the statutorily defined formula, CEs are allowed to negotiate sub-ceiling discounts for drugs purchased through the 340B program. States can calculate a 340B ceiling price, but they do not have access to actual CE 340B pricing to know if the state is benefitting in full from 340B program. Without actual price information, states cannot audit to ensure that they are being billed according to their state's 340B reimbursement policy.

Issue 8: "Shared Savings" Models

Shared savings models have been suggested as a way to resolve some financial issues for states concerned about the financial impacts of 340B prescriptions' exclusion from the Medicaid rebate program. In theory, a shared savings arrangement could result in savings for the Medicaid program *if* the 340B price is generally lower than the Medicaid price net of rebates, including supplemental rebates. Still, savings could be difficult to calculate since Medicaid cannot share rebate information with CEs and CEs cannot share 340B pricing with Medicaid. Notably, the concept of shared savings and enhanced dispensing fees has been a particularly difficult issue with specialty drugs.

At this time states currently lack sufficient clarity from CMS regarding acceptable approaches for a "shared savings" model. Discrepancies between HRSA and CMS rules can also make developing a shared savings model difficult.

Issue 9: Claims Reimbursement for Outpatient Hospital Administered Drugs

Many states use acquisition cost reimbursement for 340B and published rates or Average Sales Price (ASP) pricing for other claims. However, hospital chargemasters do not generally support billing different payers at different rates, which makes billing compliance challenging for hospitals. At the same time, Medicaid programs are unable to enforce an acquisition cost based reimbursement policy on 340B entities without incurring significant administrative costs and burden in the forms of audits or other post-payment reviews.

Additionally, as outpatient hospital departments increasingly participate in the 340B program, many states may need to reevaluate their hospital outpatient reimbursement methodologies. Currently most states reimburse hospital outpatient departments at a percentage of billed charges. State Medicaid programs need to address the reimbursement rate for outpatient hospital claims which use medications purchased through the 340B program so as to capture the cost savings associated with the 340B acquisition prices and offset the loss of the federal drug rebates.

Moving Forward: Proposed Solutions for a More Effective 340B Program

The program and the issues presented are complex, but targeted improvements could greatly improve the operational challenges between Medicaid and the 340B program. Most of these improvements can be effectuated through administrative actions by the federal agencies. All will require ongoing collaboration and communication with state Medicaid agencies to implement effectively and efficiently for states, HRSA, CMS and other stakeholders.

Effectuate Technical Enhancements to the Medicaid Exclusion File

- Work with states to develop a HRSA policy for out-of-state providers that includes notification of the carve-ins or carve-outs by the providers.
- HRSA should implement editing against the NPI number for valid formatting to reduce errors. While this will not eliminate keying errors, it will reduce them. HRSA should also consider a double exam entry requirement on Medicaid Identification Numbers to try to reduce keying errors.
- Publish a quarterly file which identifies the list of CE changes, with clear descriptions of what changed.
- Maintain congruency between the NPI associated with a given provider/340B ID on the Medicaid Exclusion File with the NPIs shown in that provider's Covered Entity File. The effective date of a provider's status on the 340B exclusion list must be clear, and retroactive changes to the file must be limited to reduce complications to the drug rebate process.
    - If a CE must make a retroactive change to the file, HRSA should require the CE to notify all impacted state Medicaid agencies and HRSA prior to implementing the change.
    - HRSA should also require the CE to ensure that claims have been billed properly according to state Medicaid agency policy prior to implementing the change, then make claim changes promptly in accordance with the retroactive status.
- Develop guidelines to address situations when CEs retroactively change their status as a result of an audit, as states may be at risk for rebates owed to manufacturers depending on the date of the retroactive change. State Medicaid programs should *not* be required to repay rebates for 340B claims erroneously billed as Medicaid carve-outs by the CE, since the appropriate carve-in exclusions were not in place.
    - HRSA should develop corrective action plans for CEs to address rebate repayments. These plans could potentially entail having the CE place accumulators associated with the claims at issue into the carve-out accumulator, and decrease the 340B accumulations due to these claims. Alternatively, for CEs whose entire inventory is purchased at 340B discount prices, a repayment process to the manufacturer to cover the discounted amount can be developed.
- Update the Pharmaceutical Pricing Agreement to limit the time that drug manufacturers have to identify potential CE violations to no more than 3 years. After 3 years, it becomes difficult to effectively resolve any "duplicate discount" violations. The 340B program would be strengthened if drug manufacturers where required to identify potential "duplicate discount"

violations earlier and conduct CE audits as allowed under their contract with HRSA. Only the drug manufacturer and CE know when and if 340B drugs were purchased and possibly used for the beneficiary.

- Encourage drug manufacturers to work with CEs to prevent the "duplicate discount." Only the CE and the drug manufacturer know which, if any, drugs are being purchased under the 340B program.
- The federal agencies should collaborate with states on ways to better facilitate CE communication with Medicaid programs.

Facilitate Claims-level Identification of 340B-procured Prescriptions

- The federal agencies should collaborate with states to promote effective practices for claims identification, such as creating a resource of effective practices, including the use appropriate fields within the HIPAA-named claims processing standards.
- Collaborate with states and stakeholders on approaches to differentiate the managed care entities' commercial and Medicare Part D business from the Medicaid business. For example, as a best practices, Medicaid managed care entities and their PBMs could use a BIN/PCN combination which is unique and identifiable from the BIN/PCN combinations used for their commercial or Medicare Part D business. Additionally, states believe additional research is still needed to address the duplicate discount issue.

Issue Clear Guidance and Strengthen Enforcement Practices

- Collaborate with states to develop clear guidance regarding the interpretation of the ACA provision related to Medicaid managed care rebates and 340B-procured prescription drugs.
- Undertake timely audits of CE policy and procedures.
- Enforce the regulatory requirement that CEs, Medicaid agencies, and HRSA work together to properly identify and exclude claims from contract pharmacies.
- Strengthen accountability mechanisms to ensure CEs monitor their contract pharmacies and their 340B administrators for properly identifying 340B claims for both FFS and managed Medicaid so that duplicate discounts can be avoided.
- Establish a mechanism to ensure timely collaboration between the federal agencies and states regarding changes to 340B, especially in areas where there may be conflict between mandates, guidance or regulations from the two federal agencies.
- Provide input opportunities and sufficient implementation time for any necessary system changes. Changes to federal rules and regulations have a significant impact on the operations of both the CEs and Medicaid agencies.

Improve Transparency Related to Reimbursement and Clearly Articulate Expectations

- State Medicaid agencies understand and are sympathetic to the need for confidentiality in pricing agreements. However, other options should be explored to protect the integrity of the

programs. For example, policymakers should consider the creation of an "average 340B acquisition price" that could be shared with the states.

- Engage states in discussion around the complex issues involved in developing "shared savings" models. States are particularly interested in further engagement with CMS regarding options within a state plan amendment for shared savings or other reimbursement expectations.

Conclusion

The 340B and Medicaid programs play a significant role in ensuring access to vital health care services for populations in need. Both programs have also grown significantly as a result of the ACA. With the continued growth comes a need for better coordination between the two programs. CMS and HRSA must to work together to provide states with the guidance, tools, and transparency necessary to ensure that the two programs can complement each other to serve those most in need of pharmacy services.