

A Comprehensive Review of the Federal 340B Drug Discount Program

Idaho State Bar Association

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Disclaimer

- The speaker represents 340B providers, 340B provider groups, Medicaid agencies, Medicaid managed care plans and other Medicaid-related organizations
- This presentation is not to be construed or relied upon as legal advice

Overview

- 340B Primer
- Covered Entity Restrictions
- Affordable Care Act
- Bipartisan Budget Act of 2015
- Medicaid Rulemaking
- ADR Proposed Rule
- HRSA Audit Update
- Mega-Guidance
- Other 340B Developments
- SMART-D

340B Primer: Background

- 340B drug discount program requires pharmaceutical manufacturers participating in the Medicaid program to provide discounts on covered outpatient drugs purchased by federally-funded clinics and other safety net providers referred to as “covered entities” (CEs)
- The rights and obligations of CE and manufacturers are set forth in Section 340B of the Public Health Service Act (PHSA)
- Section 1927 of the Social Security Act (SSA) requires manufacturers to enter into a pharmaceutical pricing agreement (PPA) with the Secretary of Health and Human Services (HHS) as a condition of Medicaid and Medicare Part B covering the companies’ outpatient drugs

340B Primer: Background (cont'd)

- Program is administered by the Health Resources and Services Administration (HRSA) through the Office of Pharmacy Affairs (OPA)
- Because several aspects of the 340B program depend on interpretation and application of SSA provisions (e.g. average manufacturer price, best price, etc.), the Centers for Medicare & Medicaid Services (CMS) also plays a significant role in 340B program administration
- Two HRSA contractors: Apexus and American Pharmacists Association (APhA). Apexus runs the Prime Vendor Program (PVP).

340B Primer: Covered Entities

- Originally 12 categories of CEs:
 - high-Medicaid disproportionate share (DSH) hospitals owned by or under contract with state or local government
 - community health centers
 - ADAPs
 - family planning clinics
 - AIDS, TB and STD clinics
 - and other PHSA grantees
- The non-hospital CEs are only permitted to purchase and use 340B-discounted drugs within the scope of their 340B-qualifying federal grants, e.g. HIV, TB, STD, family planning, and other grant programs

340B Primer: Covered Entities (cont'd)

- Affordable Care Act (ACA) added five new categories of hospitals eligible for 340B:
 - Free-standing children's hospitals with DSH adjustment > 11.75%
 - Free-standing cancer hospitals with DSH adjustment > 11.75%
 - Critical access hospitals
 - Sole community hospitals and rural referral centers with DSH adjustment $\geq 8\%$
- All 340B hospitals must either be publicly owned or be a private nonprofit contracting with a state or local government to provide indigent care

340B Primer: Covered Entities (cont'd)

- DSH, children's and cancer hospitals are subject to a unique eligibility requirement, namely, they are prohibited from purchasing covered outpatient drugs through a group purchasing organization (GPO) or other group purchasing arrangement. PHSA 340B(a)(4)(L)(iii)
- For hospitals that use replenishment-based virtual inventory systems, initial purchases of an NDC must be on a non-340B, non-GPO account, typically at wholesale acquisition cost (WAC), and replenishment under the hospital's 340B and GPO accounts must be for the same NDC (including package size) as for the drugs dispensed or administered. See HRSA Release No. 2013-1, Statutory Prohibition on Group Purchasing Organization Participation (2/7/13)

340B Primer: Calculating Ceiling Price

- 340B ceiling price = average manufacturer price (AMP) minus unit rebate amount (URA)
- Special procedures for calculating 340B price for new drugs:
 - Manufacturers must estimate a new drug's 340B ceiling price for the first 3 quarters that the drug is on the market
 - After 3 quarters, manufacturers will have AMP and best price data to calculate the ceiling price
- Penny prices –If URA exceeds AMP, then the manufacturer must charge a penny for the drug. See HRSA Release No. 2011-2, Clarification of Penny Pricing Policy (11/21/11)

340B Primer: Covered Entity Restrictions

- Medicaid billing procedures may need to be adjusted to avoid manufacturers giving duplicate discounts
- Use of 340B drugs limited to “patients” of CE
- CEs must maintain auditable records
- Penalties applicable to CEs:
 - Repay 340B discounts for diversion or duplicate discount violations, with interest if violation is knowing and intentional
 - Termination if violation is knowing, intentional, systematic and egregious
 - Termination for GPO exclusion violation
 - Criminal sanctions under Prescription Drug Marketing Act

340B Primer: Contract Pharmacies

- HRSA recognized the difficulties facing 340B covered entities that lack in-house pharmacies (11,000 as of late 1996)
- In 1996, HRSA issued guidelines approving the use of contract pharmacies to dispense 340B drugs and requiring manufacturers to offer 340B pricing on drugs dispensed by contract pharmacies to 340B-eligible patients
- Patients may choose to obtain drugs from any pharmacy, not just the contract pharmacy
- The covered entity must use a “ship to/bill to” arrangement so that drugs are purchased by the CE but sent to the contract pharmacy

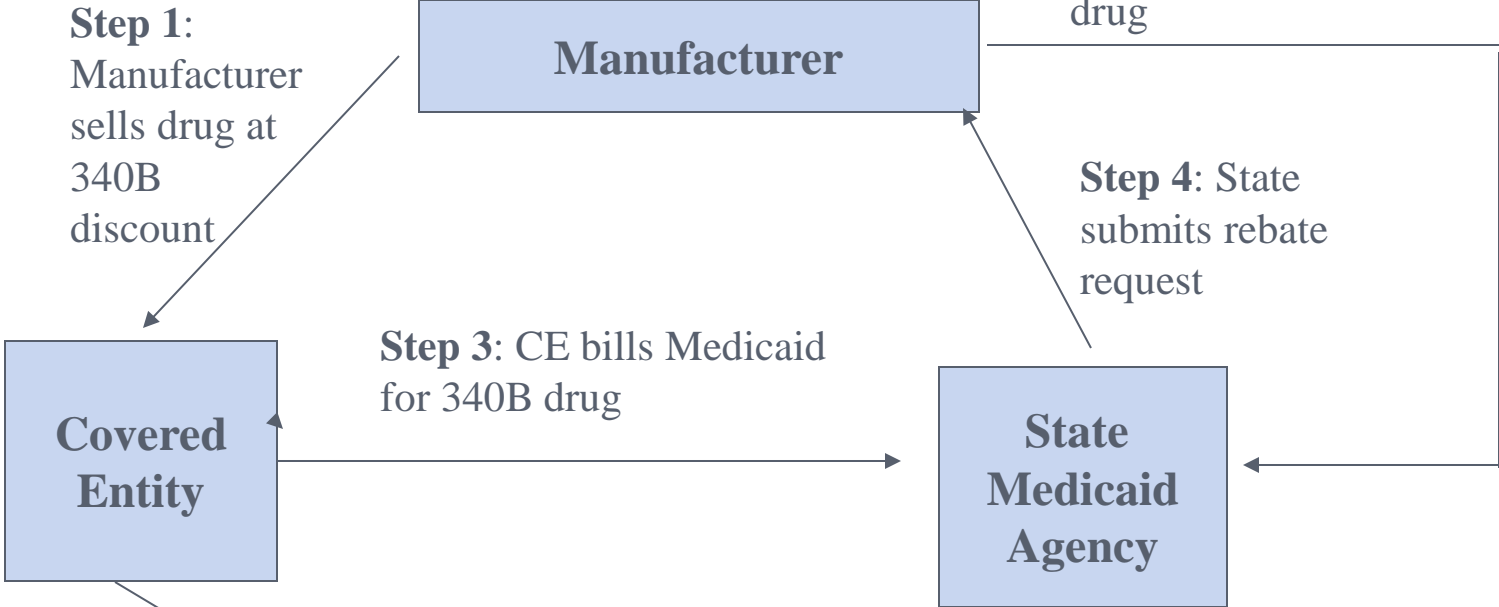
340B Primer: Contract Pharmacies (cont'd)

- The CE is responsible for the contract pharmacy's compliance with 340B requirements
- The CE must self-certify to HRSA that the contract pharmacy arrangement meets 340B program requirements
- The CE must submit information about the contract pharmacy for use in HRSA's website database
- Effective April 5, 2010, the 340B contract pharmacy program was expanded such that CEs are no longer limited to one contract pharmacy arrangement. See 75 Fed. Reg. 10272 (3/5/10).
- Right of HRSA and manufacturers to audit CEs extends to their contract pharmacy arrangements

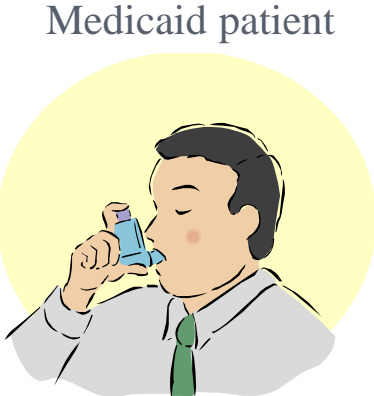
CE Restrictions: Duplicate Discounts

- CEs usually must change their Medicaid billing practices for 340B drugs but are not required by the government to change their billing practices for other payers
- With respect to Medicaid, 340B drugs are reimbursed at actual acquisition cost (AAC) when dispensed by pharmacies in the retail setting and billed on a fee-for-service (FFS) basis
- The sole reason that CEs must adjust their Medicaid billing practices is to protect manufacturers from the duplicate discount problem

CE Restrictions: Duplicate Discounts (cont'd)



Step 2: 340B drug is dispensed to Medicaid patient



STEPS 1 AND 5 = DUPLICATE DISCOUNT



CE Restrictions: Duplicate Discounts (cont'd)

Options	Covered Entity Procedures	State Medicaid Procedures
Medicaid Carve-In for Retail FFS Drugs	Bills state at AAC or reduced rate and submits pharmacy's Medicaid billing number to HRSA for posting on website	Using HRSA's exclusion file, state excludes from rebate requests any claims paid under billing number posted on HRSA website
Medicaid Carve-Out for Retail FFS Drugs	Purchases its Medicaid outpatient drugs outside 340B program, withholds billing number from HRSA website and bills Medicaid at regular non-340B rates	State includes CE's claims in rebate request files
Shared Savings	Same as carve-in option except entity and state enter into alternative billing and payment arrangements	Pays based on shared savings arrangement



CE Restrictions: Anti-Diversion

- “A covered entity shall not resell or otherwise transfer the [340B-discounted] drug to a person who is not a patient of the entity.” PHSA 340B(a)(5)(B)
- HRSA has established a three-pronged test for evaluating whether an individual falls within the definition of a “patient.” 61 Fed. Reg. 55,156 (10/24/96)
- An individual is not a “patient” if the only service received from the CE is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting. 61 Fed. Reg. 55,156 (10/24/96)



CE Restrictions: Anti-Diversion (cont'd)

1. The CE has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and
2. The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity; and
3. The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or federally-qualified health center look-alike status has been provided to the entity.

CE Restrictions: Anti-Diversion (cont'd)

- ADAP patients – an individual registered in a state operated or funded AIDS drug purchasing assistance program receiving financial assistance under title XXVI of the PHSA will be considered a “patient” of the covered entity for purposes of this definition if so registered as eligible by the state program
- Hospital patients
 - Third prong of patient definition does not apply
 - Purchase of 340B drugs for inpatient use or in violation of the orphan drug exclusion is considered diversion

ACA: Medicaid Changes

- ACA extended Medicaid rebate program to drugs covered by managed care organizations (MCOs) unless purchased through 340B
 - MCO drugs are not rebatable when purchased through 340B program. SSA 1927(j)
 - HRSA has clarified that the Medicaid exclusion file does not apply to MCO claims
 - How 340B drugs are billed and reimbursed is generally a matter of private negotiation between the CE (or its pharmacy) and the MCO (or its pharmacy benefit manager)
- According to the HHS Office of Inspector General (OIG), states' success at establishing systems to exclude 340B MCO claims from rebate requests has been mixed



ACA: Integrity Provisions

- HHS must issue regulations to establish a formal alternative dispute resolution (ADR) process
- Current process is voluntary and outcomes are not legally binding
- Must exhaust this process before proceeding to court
- Both manufacturers and CEs must use this process
- HRSA issued a proposed ADR regulation this summer and the comment period closed on October 11. 81 Fed. Reg. 53381 (8/12/16)
- HRSA received thirty-one comments

ACA: Integrity Provisions (cont'd)

- HHS is also required to make 340B ceiling prices available to CEs and to develop a system for verifying the accuracy of 340B price calculations
- OPA posted on its website an update on a new pricing system “designed to calculate, verify and display 340B ceiling prices.”
 - **Verification** – Manufacturers will upload their quarterly pricing data to validate their prices with the HRSA-verified 340B ceiling prices
 - **CE access to pricing** – CEs will be assigned log-in credentials to view 340B ceiling prices on a password-protected website
- In December 2015, OPA provided on its website a link to a sample notification form for informing the government when 340B prices are unavailable

ACA: Integrity Provisions (cont'd)

- Manufacturers are subject to civil monetary penalties (CMPs) for “knowing and intentional” overcharges, and HRSA issued this year a final rule implementing this provision
 - Delegates authority to the OIG to enforce
 - Imposes up to \$5,000 for each “instance of overcharging” which is defined on a per-order basis
 - Obligation to issue refunds for over-estimating 340B price for new drugs no longer be conditioned on a request by CE

82 Fed. Reg. 1210 (1/5/17)

- HRSA’s final rule also addressed what it means for an overcharge to be “knowing and intentional” when the overcharge is inadvertent or manufacturer acted on reasonable interpretation of agency guidance. See 82 Fed. Reg. 1220-22

ACA: Integrity Provisions (cont'd)

- HRSA also addressed two pricing issues in the final rule
 - ***Penny pricing*** – ceiling price set at \$0.01 if calculation of ceiling price results in less than \$0.01
 - ***New drugs*** – estimate ceiling using 340B discount off of WAC until AMP is available
- Following the Trump Administration's regulatory freeze, HRSA delayed the effective date to May 22, 2017 and has solicited comments on whether the rule should be delayed further to October 1, 2017
- HHS is also required to issue guidance on the refund process for overcharges
- Under the ACA, refunds are owed to CEs in the event of an overcharge, including when AMP and best price are restated



ACA: Integrity Provisions (cont'd)

- Drug manufacturers must allocate drugs in short supply in a non-discriminatory manner
 - HRSA advises manufacturers to develop a plan for non-discriminatory, restricted distribution to all purchasers, including 340B providers
 - Where feasible, manufacturers should notify OPA in writing 4 weeks before implementation date
 - Allocation plans are published on OPA website
- See HRSA Release No. 2011-1.1, Clarification of Non-Discrimination Policy (3/23/12)



ACA: PPA Changes

- In August 2016, OMB approved an addendum to the PPA. See OMB Information Collection Request, Control No: 0915-0327 (8/23/16)
- The addendum incorporates into the PPA two manufacturer program integrity provisions passed under the ACA:
 - Manufacturers must make quarterly reports to HHS of 340B ceiling prices for covered outpatient drugs; and
 - Manufacturers must offer covered entities the opportunity to purchase a drug at or below the ceiling price if the drug is available to another purchaser at any price.
- The addendum is available on the OPA website



ACA: Recertification

- Focus of recertification is that CE information on OPA database is accurate and up to date
- Two-step process in which CEs have to:
 - Correct information for existing sites and/or decertify sites that no longer exist or use 340B drugs
 - Certify that CE meets eight 340B compliance standards, including duty to disclose to OPA any material breach of a 340B requirement
- New recertification forms have dropped the materiality language but OPA website still directs CEs to report material violations

ACA: Orphan Drug Exclusion

- “Orphan drugs” are excluded from scope of covered outpatient drugs subject to 340B discounts for newly-eligible rural and cancer hospitals
- “Orphan drugs”
 - (1) are designed to treat rare diseases and conditions that affect fewer than 200,000 patients in the U.S. or,
 - (2) if the disease or condition affects more than 200,000 patients in the U.S., will produce sales that fail to cover R&D costs
- Congress removed children’s hospital from the ban pursuant to post-ACA legislation

ACA: Orphan Drug Exclusion (cont'd)

- HRSA issued a regulation that would limit the prohibition "to uses for the rare disease or condition for which the orphan drug was designated." 78 Fed. Reg. 44016 (7/23/13)
- The rule was enjoined as a result of a lawsuit by PhRMA. *PhRMA v. HHS*, 43 F.Supp.3d 28 (D.D.C. 2014). HRSA issued the same policy as an interpretive rule which was also overturned. *PhRMA v. HHS*, No. 14-1685, Mem. Op. (D.D.C. 10/14/15)
- OPA recently clarified on its website that manufacturers may voluntarily offer 340B prices on orphan drugs

Bipartisan Budget Act of 2015: Sec 602

- Applies the Medicaid additional rebate requirement to generic drugs
- Increases 340B discounts for generic drugs because
 - the additional rebate will increase generic drugs' URA, and
 - $340B \text{ ceiling price} = AMP \text{ minus URA}$
- Additional 340B savings was included in budget score by Congressional Budget Office
- Generic drugs will be subject to penny pricing like brand names

Bipartisan Budget Act of 2015: Sec 603

- Establishes “site-neutral” Medicare reimbursement to new off-campus outpatient departments of a provider
- Effective January 1, 2017, off-campus facilities acquired by a hospital after the budget bill’s date of enactment (11/2/15) will not be reimbursed by Medicare under the hospital outpatient payment system; they will continue to be paid based on their pre-acquisition status
- Recent hospital outpatient prospective payment final rule contains language strongly suggesting that Section 603 will not impact 340B hospitals and registration of their offsite clinics



Medicaid Rulemaking: Covered Outpatient Drugs

- Several parts of AMP rule address 340B program. 81 Fed. Reg. 5170 (2/1/16)
- States must file state plan amendments (SPAs) by June 30, 2017 providing 340B-specific reimbursement policies based on AAC
 - Only applies to retail FFS drugs
 - Does not apply to physician administered drugs nor to Medicaid MCO drugs
- All sales to CEs are exempt from best price
- Acknowledges manufacturer obligation to refund CEs when restating AMP and/or best price, but clarified that this issue must be addressed by HRSA



Medicaid Rulemaking: Managed Care

- Medicaid managed care rule also addresses 340B program. 81 Fed. Reg. 27498 (5/6/16)
- States have flexibility in identifying 340B MCO claims and excluding such claims from their rebate requests
 - CMS declined to establish a standardized process for identifying 340B MCO claims
 - CMS declined to affirm the obligation of states to avoid duplicate discounts involving 340B MCO claims. CMS opined that states, MCOs and CEs all have a role to play in avoiding duplicate discounts.
- CMS clarified that CEs may identify 340B MCO claims directly with states rather than through MCOs. See, e.g., billing arrangements in Oregon and Hawaii.



Medicaid Rulemaking: Managed Care (cont'd)

- OIG published study in June analyzing state efforts to exclude 340B drugs from Medicaid MCO rebate requests
- OIG found that, to identify 340B drug claims and correctly collect rebates for MCO drugs, most states use methods that identify providers using 340B-purchased drugs.
- However, provider-level methods may not accurately identify all individual 340B drug claims, creating a risk of duplicate discounts and forgone rebates.
- By contrast, methods that operate at the claim level can improve accuracy in identifying 340B drug claims, and thereby, help states correctly collect rebates
- OIG recommended that CMS require states to use claim-level methods to identify 340B claims, but CMS did not concur



Medicaid Rulemaking: Evolving State 340B Policies

- In response to AMP and MCO rules, states are focusing on their 340B billing and reimbursement policies
- Some states have pursued policies that are problematic for CEs
 - Mandatory carve-out (e.g., DE)
 - Mandatory carve-in and AAC reimbursement (e.g., CA, IL)
- Other states have adopted 340B-friendly solutions
 - Claims-level carve-in model for retail FFS and MCO drugs (e.g., OR)
 - Claims-level carve-in model for FFS physician administered drugs (e.g., OK)

ADR Proposed Rule: Comparison of Comments

ADR Proposal	PhRMA	BIO	Covered Entities
Preconditions for finalizing rule	No ADR process until audit guidelines, manufacturer refund process, ceiling price, civil monetary penalties, and mega-guidance are in place	No ADR process until ceiling price, manufacturer refund process and standardized CE identification system is in place	No preconditions
ADR panel	One or three administrative law judges (ALJs); no HRSA representation or voting rights	One ALJ or a panel of ALJs or, as a fallback, a panel of three non-ALJs; no OPA representation or voting rights	Panel of three non-ALJ government employees drawn from a roster of seven; no OPA or PVP representation or voting rights
Confidentiality	Standards are needed to protect confidential business information; protective orders must be issued	Safeguards are needed to protect confidential business information; panelists should sign non-disclosure agreements	Safeguards are needed to protect confidential business information; safeguards are needed to comply with patient privacy laws



ADR Proposed Rule: Comparison of Comments (cont'd)

ADR Proposal	PhRMA	BIO	Covered Entities
Manufacturer claims permitted	CE eligibility claims (e.g., GPO prohibition claims) should be allowed; manufacturer audit prerequisite can be satisfied by audits performed by other manufacturers	Should accommodate the other kinds of disputes described in HRSA's 1996 voluntary ADR guidelines; manufacturer audit prerequisite can be satisfied by audits performed by other manufacturers	Should only address diversion and duplicate discount claims and should exclude Medicaid managed care duplicate discount claims; manufacturer audit prerequisite may not be satisfied by other manufacturer audits
CE claims permitted	No second guessing accuracy of prices in HRSA's password protected ceiling price system	No access to underlying price reporting metrics, i.e., AMP or Best Price	Should accommodate claims that ceiling prices are based on incorrect data such as AMP or Best Price
Three year statute of limitations	Tolled while audit is being performed	Three years begins when audit completed or other kinds of extensions are needed to accommodate length of audit	Three years begins on the date of sale or payment at issue except manufacturer restatements of AMP, Best Price, etc.



ADR Proposed Rule: Comparison of Comments (cont'd)

ADR Proposal	PhRMA	BIO	Covered Entities
Consolidation of claims	CE claims must involve substantially the same NDCs and quarters; manufacturer claims can be based on the same policy or practice by CE and can be brought by a trade association or other agent	CE and manufacturer claims should be evaluated against the same standard – whether the claims present common questions of law or fact and whether consolidation would be more efficient and address fairness concerns	CE claims should not require complete commonality of NDCs; manufacturer claims must be based on the same facts and cannot be brought by trade association or other agent
Time to respond to claim	Sixty (60) days with extensions	At least sixty (60) days with extensions	At least forty five (45) days with extensions
Information requests	Manufacturers should not be responsible for obtaining information from third parties and should be allowed to submit their own information requests	Manufacturers should not be responsible for obtaining information from third parties and ADR panel should hold preliminary hearing to establish the scope of discovery	Manufacturers should be responsible for obtaining information from third parties; CEs should be entitled to receive AMP and Best Price data if confidentiality is protected; ADR panel should hold briefing on overcharge data



ADR Proposed Rule: Comparison of Comments (cont'd)

ADR Proposal	PhRMA	BIO	Covered Entities
Decision making	Panel should share draft report prior to issuing final decision and a summary of the decision should be published	Panel should share draft report prior to issuing final decision; summary of decision should be published unless parties agree that it should not be	Panel should share draft report prior to issuing final decision; decision should be issued within six months after briefing concluded; HRSA should seek public comment on whether to publish summaries of decisions
Enforcement	HRSA should enforce decision after giving notice to affected party	HRSA should enforce decision	HRSA should enforce decision



HRSA Audit Update

- As of last month, HRSA audit reports posted:
 - 51 audits for FY 2012
 - 94 audits for FY 2013
 - 99 audits for FY 2014
 - 200 audits for FY 2015
 - 182 audits for FY 2016
 - 6 audits for FY 2017
- To date, HRSA has conducted four manufacturer audits

HRSA Audit Update (cont'd)

- In January 2016, OPA provided an update on its website announcing changes to the audit process
 - Discontinuance of public letter requirement
 - Electronic submission of audit documents using email address 340baudit@hrsa.gov
 - Corrective action plans (CAPs) remain open until settlements have been finalized and CE submits letter attesting that corrective action is complete
 - CEs must receive written confirmation from state Medicaid agencies that manufacturers were not subject to duplicate discounts
- HRSA now provides CAP template to assist CEs with preparing CAPs

Mega-Guidance

- HRSA's long-awaited 340B omnibus guidance was issued in August 2015. 80 Fed. Reg. 52300 (8/28/15)
- Comments are posted at:
<http://www.regulations.gov/#!docketBrowser;rpp=50;po=0;dct=PS;D=HRSA-2015-0002>
- The Mega-Guidance addresses almost every aspect of the 340B program
- More than 1,200 comments were submitted
- HRSA transmitted the final Mega-Guidance to OMB on September 1, 2016 for final approval, but withdrew the Mega-Guidance on January 30, 2017



Mega-Guidance (cont'd)

- Program eligibility and registration
 - Termination and re-enrollment
 - Recertification
 - Prohibition against group purchasing
- Drugs eligible for purchase under 340B
 - “Covered outpatient drug” definition would exclude bundled Medicaid drugs
- Individuals eligible to receive 340B drugs
 - New six-part patient definition proposal
- Other CE requirements
 - Duplicate discounts and the “presumed” carve-out of Medicaid managed care drugs by contract pharmacies
 - Auditable records



Mega-Guidance (cont'd)

- Contract pharmacies
- Manufacturer responsibilities
 - PPA
 - Obligation to offer 340B prices and application to limited distribution networks
 - Issuing refunds and credits to CEs
 - Recertification
- Rebate option for ADAPs
- Program integrity
 - HRSA audits of CEs
 - Manufacturer audits of CEs
 - HRSA audits of manufacturers and wholesalers

Mega-Guidance: CE Concerns

- Would significantly decrease volume of drugs that could be purchased through 340B
 - Prescriptions written in unregistered sites would be excluded
 - For hospitals, guidance would disqualify (a) discharge prescriptions, (b) infusions ordered outside hospital and (c) pre-admission drugs
 - Drugs paid for by Medicaid in a bundled manner would be disqualified
 - Medicaid MCO drugs dispensed by contract pharmacies would be “presumed” to be carved out
- Would significantly increase administrative burden
 - Patient definition would require satisfying six tests rather than three
 - Contract pharmacy registration and oversight



Mega-Guidance: Manufacturer Concerns

- Does not go far enough in overseeing and controlling growth of contract pharmacies
- Notification of HRSA of limited distribution networks prior to implementation would be burdensome and unauthorized
- Would require calculation of refunds by NDC and would prohibit calculations based on other methods, e.g., aggregate or net purchases or using *de minimus* thresholds
- Increased reporting standards would be burdensome

SMART-D: Background

- The Center for Evidence-Based Policy (CEbP) at Oregon Health & Science University recently launched a three-year, three phase pilot program funded by the Laura and John Arnold Foundation. The program's purpose is:
 - to strengthen the ability of Medicaid programs to manage prescription drugs through alternative payment methodologies, and
 - to provide Medicaid leaders with opportunities to shape the national conversation on prescription drug innovation, access, and affordability

SMART-D: Project Objectives

1. Map the landscape of Medicaid drug purchasing
2. Identify alternative payment options for states
3. Work to increase patient access and improve health outcomes
4. Identify specific opportunities to collaborate with drug manufacturers
5. Provide technical assistance and support to states for implementation

SMART-D: Website and Reports



STATE MEDICAID ALTERNATIVE REIMBURSEMENT AND PURCHASING TEST FOR HIGH-COST DRUGS (SMART-D)

ABOUT SMART-D HIGH-COST SPECIALTY DRUGS AND MEDICAID RESEARCH AND REPORTS NEWS CONTACT



OUR PURPOSE IS TO **HELP BRING CLARITY** TO THE COMPLICATED LANDSCAPE OF **DRUG PURCHASING** FOR STATE MEDICAID PROGRAMS AND PROVIDE **ALTERNATIVE PAYMENT MODELS (APMS)** TO HELP **IMPROVE PATIENT ACCESS** TO EVIDENCE-BASED THERAPIES WHILE ALLOWING STATES TO **PREDICT AND MANAGE PRESCRIPTION DRUG COSTS.**

[LEARN MORE ABOUT SMART-D](#)

- See www.smart-d.org
- Research and reports tab:
 1. Summary Report
 2. Legal Brief
 3. Economic Analysis
 4. APM Brief
 5. MED Policy Report

SMART-D: Elements Needed to Establish Alternative Payment Models and Value-Based Purchasing Arrangements

Manufacturer APM Elements

- adjustable pricing
- indication-specific pricing
- closed formulary
- prior authorization
- Medicaid best price exemption

Provider VBP Elements

- adjustable reimbursement rates
- sole source contracting
- prescription limits
- adjustable patient cost-sharing

SMART-D: Federal Impediments

- Medicaid Drug Rebate Program (MDRP)
 - rebate calculation is statutorily fixed
 - rebates are NDC-specific, not indication-specific
 - states may not use closed formularies, although preferred drug lists (PDLs) are allowed
 - prescription limits are regulated
- Medicaid Non-MDRP
 - AAC reimbursement for FFS retail drugs under AMP rule
 - patient cost-sharing, anti-kickback, etc.

SMART-D: State and Manufacturer Opportunities

- ***Pathway One – Supplemental Rebate Arrangements:*** Use of PDLs and prior authorization to negotiate supplemental rebates with manufacturers on FFS drugs
- ***Pathway Two – MCO Contracting:*** State outsources to MCOs the task of negotiating supplemental rebates
- ***Pathway Three – MCO/340B Covered Entity Partnerships:*** Enter into APM rebate arrangements with manufacturers and VBP arrangements with 340B providers/pharmacies for 340B drugs reimbursed by state's MCOs
- ***Pathway Four – Hospital-Dispensed Covered Outpatient:*** Enter into manufacturer APM rebate and provider VBP arrangements for covered outpatient drugs dispensed by hospitals and billed at no more than their purchasing costs

SMART-D: State and Manufacturer Opportunities (cont'd)

- ***Pathway Five – Physician Administered Drugs That Fall Outside “Covered Outpatient Drug” Definition:*** Enter into manufacturer APM rebate and provider VBP arrangements for PADs that fall outside “covered outpatient drug” definition
- ***Pathway Six – Section 1927 Alternative Benefit Plans:*** Establish closed formulary for drugs provided to Medicaid expansion populations that receive essential health benefits under Affordable Care Act
- ***Pathway Seven – Section 1115 Waiver:*** Seek to relax formulary restrictions and other MDRP requirements in order to test new VBP models for prescription drugs and related services
- ***Pathway Eight – 340B with Innovative Care Delivery Models:*** Work with CEs to implement innovative patient care delivery models and shared savings arrangements leveraging 340B discounted pricing

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IDAHO REPUBLICANS PRESENT NEW HEALTH PLAN

AP

March 14, 2017 at 2:03 pm | By BILL DENTZER

Draft legislation emerging in the Idaho House seeks to meet primary care shortages and cut costs across the state health care system.

Central to the proposal is the premise that health care is too expensive across the entire system, driven largely by shortages in primary care services that make people delay care until their health worsens or seek emergency room treatment regardless of urgency.

The “Idaho Accountable Community Care Act” seeks to change that dynamic while addressing the longstanding issue of how to provide care to low-income Idahoans. It would provide a state-funded solution that preserves Idaho’s options for seeking federal assistance under the existing or revised federal health care framework.

It builds on earlier proposals to provide \$10 million from the state’s tobacco settlement funds to cover primary care and prescriptions for a segment of the low-income population caught in the health coverage gap. Some 78,000 Idahoans at or below the federal poverty level don’t qualify for Medicaid or for subsidized insurance on the state exchange.

Idaho lawmakers have resisted expanding Medicaid to cover the gap group, a key provision of the 2010 Affordable Care Act. Republican plans in Washington to replace the ACA call for phasing out Medicaid expansion over time and converting Medicaid payments to states to fixed block grants.

The Idaho proposal, fleshed out over the past month by a half-dozen Republican lawmakers, was presented to the House Republican majority caucus Monday and is expected to work its way through the Legislature this week. It could either be introduced in the House through the normal committee process or be used to rewrite an existing bill awaiting amendments in the Senate.

With the Legislature scheduled to adjourn next week, action on the proposal is expected to come quickly.

State-funded to start

Though based initially on state funds, the proposal does not preclude seeking other funding sources, including federal money, and in fact authorizes state health officials to pursue potential federal waivers and funding, subject to legislative approval.

But the proposal seeks to go beyond the question of providing care for low-income residents, emphasizing in an outline document that Republican control in Washington has given Idaho “freedom to building the health care system that is best for Idahoans ... from the ground up.”

“This is to try to improve primary care to everybody in Idaho,” Rep. John Vander Woude, R-Nampa, the House majority caucus chair, said Monday. “It’s not focused only on people in the gap. It’s focused on people in Medicaid, and it’s focused on our whole delivery system. ... Until we have a health care system that has reasonable costs to it, you can’t solve the problem.”

The main elements of plan:

Managed care for low-income residents: Create a “coordinated care” program to serve Medicaid recipients and the gap group. The state would cover costs for the non-Medicaid group, with enrollment subject to available funding. Priority would be given to those with one or more health conditions such as asthma, diabetes, heart disease, hypertension or obesity.

The state would contract with organizations to provide care exclusively in each of up to seven state service areas, each overseen by its own governing board. Those organizations would assign care managers to work with individuals at moderate to high risk, helping them to develop personal health care improvement plans. Accountability measures would encourage members to make healthier choices and include penalties, such as premiums or co-pays, if members fail to take advantage of them.

Lower cost prescription drugs for participants would be procured through the federal 340B discounted drug program.

More doctors: “Substantially increase” the number of family residency slots in Idaho to address primary care scarcity. The proposal directs the state Department of Health and Welfare to identify regions with a shortage of primary care doctors, determine how many are needed, and find out how to get them. It would establish a state fund similar to an existing federal program to repay physicians’ loans if they commit to staying in under-served areas.

Non-emergency care: Require hospitals to set up programs and procedures to redirect non-emergency patients to primary care providers instead of receiving expensive emergency room care.

“We want to hold the doctors or the hospitals responsible and accountable for the care they deliver,” Vander Woude said. “But we also want to hold the patient accountable for how he’s treated in his care, how he’s taking care of himself.”