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The Uncertain Future of the 340B Drug Discount Program

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Here we are in March 2017 and no one is sure where things stand with the 340B Drug Discount Program. **HRSA** and its oversight of the 340B program are subject to the **recent Executive Orders** restricting issuance of federal regulations and the promised repeal of the Affordable Care Act (ACA) has the potential to impact 340B operations. In fact, the only thing that appears certain for the 340B program is that nothing is certain. So let's review several recent 340B developments, and potential developments to come.

Omnibus Guidance

In June 2016, I **predicted in this blog** that the final version of the long-promised HRSA 340B Omnibus Guidance, which would have provided clarity on 340B program standards, would never actually be issued or implemented. And in fact, at the end of January 2017, HRSA withdrew the final 340B Omnibus Guidance while it is was still pending at OMB. Even if it had issued, the Guidance would have been subject to the terms of the regulatory freeze President Trump imposed by Executive Order immediately after his inauguration on January 20, 2017.

Setting aside the Trump administration's dim view of agency regulation, I continue to believe that the October 2015 court invalidation of HRSA's "interpretative" orphan drug rules calls into question HRSA's legal authority to issue the Guidance. A number of topics to be addressed in the Guidance, such as limiting the definition of 340B "patient", lack specific statutory authorization and were subject to challenge under the orphan drug precedent. In the absence of Congressional action, we may have seen the last of the Omnibus Guidance.

Ceiling Price and Manufacturer Penalty Regulation

On January 5, 2017, HRSA did issue its **final rule** on manufacturer calculation of 340B Drug Ceiling Prices and its authority to assess Civil Monetary Penalties on manufacturers who knowingly overcharge a 340B covered entity. This rule was to be effective on March 6, 2017, but, because of the timing of when it was issued, the rule is subject to the terms of the January 20, 2017 Executive Order governing regulations.

HRSA can cite to legislative authority to issue this rule, although the extent of that authority may still be subject to challenge. In truth, the effect of the Executive Order will be negligible, delaying the effective date of the rule to March 21, 2017. Moreover, HRSA had already **announced** that since the effective date of this rule fell within the middle of a quarter, HRSA would not enforce the rule until the start of the next quarter, April 1, 2017.

Medicaid AAC

The **Medicaid Covered Outpatient Drug Rule** was issued in February 2016, and is unaffected by the recent Executive Orders. As I **blogged** about at the time, this rule has major implications for 340B.

Under the rule, states have until April 1, 2017 to submit a new State Medicaid Plan amendment that complies with the requirement that Medicaid reimbursement for drugs be based on the Actual Acquisition Cost (AAC) of the drug. While CMS did give states several options to develop AAC, there was no flexibility in AAC calculation for 340B drugs. For 340B drugs provided to Medicaid patients, AAC is going to be the cost the covered entity paid for the drug, which will be capped at the 340B ceiling price. **As CMS** told state Medicaid directors: "in accordance with the requirements in §447.518(a)(2), the state's [Medicaid] payment methodology for drugs dispensed by 340B covered entities, 340B contract pharmacies, and I/T/U pharmacies must be in accordance with the definition of AAC in §447.502 of the final regulation. For drugs purchased through the 340B program, reimbursement should not exceed the 340B ceiling price."

It should be noted that the AAC requirement is specific to ingredient cost, not dispensing costs. As part of the conversion to AAC, CMS instructed states to reexamine their dispensing costs. In states that have already implemented AAC, dispensing fees were in fact increased, as best illustrated by the most recent **CMS report** on state Medicaid drug reimbursement methodologies. For example, as of September 2016:

- Arkansas was still using an AWP-based Medicaid reimbursement methodology with a dispensing fee of $5.51, while Iowa had moved to an AAC-based Medicaid reimbursement and increased dispensing fees to $11.73.
- Several states already using AAC for Medicaid reimbursement had enhanced dispensing fees involving a tiering based on pharmacy volume, including Colorado, Idaho and Oregon.
- Several states have enhanced Medicaid dispensing fees specific to 340B, including Florida, Illinois and Utah.

In many states, 340B drugs may be dispensed to/billed to Medicaid. And in some states, the Medicaid program prohibits 340B covered entities and their contractors from carving out Medicaid patients from accessing 340B drugs. Covered entities will want to ensure they are aware of state regulatory changes governing Medicaid billing as AAC and accompanying CMS directives are fully implemented.

ACA Repeal

As of the writing of this blog post, the House Republicans have put out a legislative proposal, **the American Health Care Act,** to amend portions of the ACA, and repeal and replace other portions of the ACA. And within hours, numerous Republican expressed reservations about the proposal, so the future of the bill is in flux.

It is too soon to know what any final bill will look like. But it bears mention that the ACA included certain provisions that directly impacted the 340B program; depending on the language used and sections cited, repeal of the ACA could potentially repeal those provisions.

For example:

- The ACA expanded the “covered entities” eligible to participate in 340B to qualifying children’s hospitals, critical access hospitals, free standing cancer hospitals, sole community hospitals, and rural referral centers. Repeal of the ACA could strip these entities of eligibility to participate in 340B.

- The ACA added language exempting orphan drugs from the 340B definition of a “covered outpatient drug” and thus ineligible for 340B drug discounts. This is the same language that a court ruled was so unambiguous that HRSA’s interpretative rule-making was unnecessary and unauthorized. ACA repeal could make orphan drugs used on an out-patient basis potentially eligible for 340B pricing.

- Prior to the ACA, many states exempted drugs covered through Medicaid Managed Care Organizations (MCOs) from invoicing for Medicaid drug rebates, including any drugs provided through 340B. And those states relied on that exception in negotiating agreements with MCOs. States’ flexibility ended when the ACA mandated that drugs provided by Medicaid MCOs be included in states’ invoicing of Medicaid drug rebates. States were required to implement systems to track and report drugs provided through Medicaid MCOs and, in the case of 340B, ensure those drugs were not subject to the duplicate discount prohibition. But in the last several years, there have been multiple HRSA audits and reporting about increasing problems with duplicate discounts in 340B drugs provided through Medicaid MCOs. An HHS-OIG **review** found that 340B contract pharmacies frequently lack adequate processes to even identify patients covered by Medicaid MCOs. So some states, Medicaid MCOs, covered entities, and their contract pharmacies may welcome repeal of the mandate that drugs dispensed by Medicaid MCOs be included in state invoicing for Medicaid drug rebates.

What Could Happen Next?

It has been almost two years since the last **Congressional hearing on 340B** but interest in the program has not waned. It is within the realm of possibility that Congress could take affirmative action on the program. Proposals previously floated have included:

- Further changes to government program reimbursement for 340B drugs so that government safety net programs share in 340B savings. The AAC directive impacted Medicaid reimbursement. But Medicare still pays significantly more for 340B drugs than the covered entity's acquisition cost. The profits are especially steep for physician administered drugs where Medicare Part B reimburses the provider for the drug cost and provides separate reimbursement for the administration procedure. OIG has **reported** that if in 2013, Medicare Part B based drug cost reimbursement for 340B drugs at ceiling price plus 6% of ASP to cover overhead, Medicare would have saved $850 million in drug costs and beneficiaries would have saved $213 million in co-pays.

- Authorizing state Medicaid program access to 340B prices, so that Medicaid programs can better audit for compliance with 340B billing requirements.

- Requiring that covered entities and their contractors actually make 340B drugs available to uninsured patients.

- Mandating transparency in the profits individual covered entities realize from 340B, and how the covered entity actually uses the resulting profits.
- Providing clarity on the 340B program operations and requirements, including the definition of a 340B patient, and perhaps specifically authorizing HRSA to engage in rulemaking to provide further clarity.
- Authorizing qualified safety net providers to use 340B drugs for both in-patient and out-patient use.

One other note about the ACA bears mention. In the wake of the implementation of ACA, the resulting significant decrease in the number of uninsured patients, and anecdotal information about the corresponding increase in covered entities' profits from 340B, some mused whether or not the 340B Program had outlived its usefulness. As it is being debated, analysis of the proposed AHCA indicates it has the potential to greatly increase the number of uninsured individuals and thus could pose a significant threat to safety net providers' bottom line. Could preserving 340B become a pawn in the debate over the AHCA?

My crystal ball is incredibly cloudy these days, and right now I am out of predictions on what will happen to the 340B Drug Discount Program. But I will be watching with interest, and blogging about developments. Stay tuned.

Authors