

# HEALTH REFORM IMPACT

## What you need to know NOW

NEWS FOR THE CLIENTS AND FRIENDS OF BASS, BERRY & SIMS PLC

### 340B Doesn't Get An "A"

August 30, 2011

A recent report from the Office of Inspector General of the Department of Health and Human Services ("OIG") illustrates the government's increased scrutiny of Medicaid prescription drug coverage under the 340B drug discount program (the "340B Program").<sup>1</sup> The report, issued on June 15, 2011, was requested by Senator Charles "Chuck" Grassley in the wake of a Federal *qui tam* lawsuit alleging that eligible health care entities<sup>2</sup> (the "Covered Entities") overcharged Medicaid for Program drugs. Ultimately, the OIG concluded that half the states do not have written policies addressing prescription drug coverage under the 340B Program and that there is a general disconnect between states and Covered Entities leading to payment errors and excess.

#### **Background**

In light of escalating drugs costs, Congress established the 340B Program to aid certain beneficiaries in gaining affordable access to drugs necessary for treatment.<sup>3</sup> Under the 340B Program, prescription drug manufacturers are required to provide covered outpatient drugs to Covered Entities at or below certain statutorily defined prices. State Medicaid agencies then reimburse the Covered Entities for the discounted drugs. The program was designed such that states would reap the savings benefit by reimbursing a Covered Entity only the amount that it paid for the 340B drug.

#### **Findings**

The OIG's report concluded that the 340B Program was not working as designed in several respects. Evidence of overpayments, lack of standardization, and outdated technology led the OIG to recommend communication and implementation changes. State Medicaid agencies have

<sup>1</sup> You may access the report here: <http://oig.hhs.gov/oei/reports/oei-05-09-00321.pdf>.

<sup>2</sup> The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (the "Healthcare Reform Law") expanded the scope of healthcare entities defined as "Covered Entities." Some examples of entities historically defined as Covered Entities include federally qualified health centers, state operated drug assistance programs, black lung clinics, urban Indian organizations, and others. Under the Healthcare Reform Law, disproportionate share hospitals, critical access hospitals, rural referral centers, children's hospitals, sole community hospitals, and free-standing cancer hospitals are all considered eligible for the 340B Program discount.

<sup>3</sup> The 340B Program was established by Section 602 of the Veterans Health Care Act of 1992 (P.L. 102-585).

historically been able to establish state-specific 340B billing policies, but have never been required by the Centers for Medicare & Medicaid Services (“CMS”) to do so. The OIG’s report confirmed that 25 states do not have established 340B billing policies and have been without the necessary resources to develop internal payment monitors to help shield against overpayments and duplicate discounts.<sup>4</sup>

### *Overpayments*

The report noted that states currently do not have access to 340B price ceiling information, making it difficult for states to validate the amount of the claim submitted by the Covered Entity. Thus, often the state will reimburse the Covered Entity for the amount of the bill even though the bill may exceed the 340B price. Often states are put in the situation of having to conduct post-pay reviews to identify overpayments instead of being able to use pre-pay edits based on available price ceiling information. This is yet another instance where the government is currently “paying and chasing” instead of stopping overpayments at the front end of the process.<sup>5</sup>

### *Duplicate Discounts*

Additionally, the report addressed the problem of duplicate discounts that occur when a pharmaceutical manufacturer provides the covered drug at a 340B discount rate and later pays the State Medicaid agency a rebate for the same drug under the Medicaid drug rebate program, which is separate from the 340B Program. There is a tool designed to prevent duplicate discounts, known as the Medicaid Exclusion File, but the OIG’s report observed that many states are using alternatives to the Medicaid Exclusion File because of concerns about inaccurate information in that file (the report also observed that the states’ alternative methods are not necessarily accurate). The Medicaid Exclusion File is intended to identify Covered Entities that provide 340B Program drugs, which in turn is designed to enable states to exclude claims by those entities from the Medicaid rebate invoices that the states send to manufacturers.

### ***OIG Recommendations***

The OIG recommended that all states create written 340B policies and that the Health Resources and Services Administration (“HRSA”), which is the entity that administers the 340B program, share 340B ceiling prices with states. The HRSA must seek legislative authority to share such pricing information.

Additionally, the OIG recommended that the HRSA instruct Covered Entities to update their information on the Medicaid Exclusion File to help maintain the accuracy of the database. The report also suggested that HRSA work directly with states to ensure that Covered Entities’ information in the Medicaid Exclusion File is correct. For example, the report stated that HRSA could obtain updated information on Covered Entities from states that have verified all or part

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<sup>4</sup> As will be discussed, a duplicate discount occurs when a pharmaceutical manufacturer provides the covered drug at a 340B discount rate and later pays the State Medicaid agency a rebate for the same drug under the Medicaid drug rebate program (which is separate from the 340B program).

<sup>5</sup> For previous issues of *Health Reform IMPACT* addressing the government’s efforts to stop “pay and chase,” see [“Pay and Chase’ No More: CMS Begins Implementing Health Reform’s Provider Enrollment Provisions.”](#) November 12, 2010, and [“More Efforts to Stop ‘Pay and Chase’: CMS Launches Predictive Modeling Technology.”](#) August 22, 2011.

of the file for their state. To assist HRSA, CMS could provide HRSA with contacts familiar with the Covered Entities in the respective states. CMS could also instruct states to notify HRSA if they find discrepancies between their records and the Medicaid Exclusion File.

CMS agreed with the report's recommendations. According to the report, CMS plans to facilitate conversations between the HRSA and states to help create a more effective and efficient 340B Program.

If you have any questions about this issue of *Health Reform IMPACT*, please contact any of the attorneys in our Healthcare Practice Group listed below.

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### Bass, Berry & Sims Healthcare Attorneys

**Philip F. Berg**  
(615) 742-7908  
[pberg@bassberry.com](mailto:pberg@bassberry.com)

**Krista T. Cooper**  
(615) 742-7734  
[kcooper@bassberry.com](mailto:kcooper@bassberry.com)

**Meredith Edwards**  
(615) 742-7823  
[medwards@bassberry.com](mailto:medwards@bassberry.com)

**Mary Beth Fortugno**  
(615) 742-7739  
[mfortugno@bassberry.com](mailto:mfortugno@bassberry.com)

**Lauren Gaffney**  
(615) 742-7824  
[lgaffney@bassberry.com](mailto:lgaffney@bassberry.com)

**Pooneh Ghiassi**  
(615) 742-7782  
[pghiassi@bassberry.com](mailto:pghiassi@bassberry.com)

**Anna Grizzle**  
(615) 742-7732  
[agrizzle@bassberry.com](mailto:agrizzle@bassberry.com)

**Elisa E. Harris**  
(615) 742-6553  
[eharris@bassberry.com](mailto:eharris@bassberry.com)

**Angela Humphreys**  
(615) 742-7852  
[ahumphreys@bassberry.com](mailto:ahumphreys@bassberry.com)

**J. James Jenkins, Jr.,  
Chair**  
(615) 742-6236  
[jjenkins@bassberry.com](mailto:jjenkins@bassberry.com)

**Seth A. Killingbeck**  
(615) 742-7707  
[skillingbeck@bassberry.com](mailto:skillingbeck@bassberry.com)

**Daniel R. Kuninsky**  
(615) 742-7837  
[dkuninsky@bassberry.com](mailto:dkuninsky@bassberry.com)

**Claire F. Miley**  
(615) 742-7847  
[cmiley@bassberry.com](mailto:cmiley@bassberry.com)

**T. Scott Noonan**  
(615) 742-6273  
[snoonan@bassberry.com](mailto:snoonan@bassberry.com)

**Shannon Pinkston**  
(615) 742-7727  
[spinkston@bassberry.com](mailto:spinkston@bassberry.com)

**Cynthia Y. Reisz**  
(615) 742-6283  
[creisz@bassberry.com](mailto:creisz@bassberry.com)

**Brian D. Roark**  
(615) 742-7753  
[broark@bassberry.com](mailto:broark@bassberry.com)

**Catherine J.B. Sloan**  
(615) 742-7789  
[csloan@bassberry.com](mailto:csloan@bassberry.com)

**Danielle M. Sloane**  
(615) 742-7763  
[dsloane@bassberry.com](mailto:dsloane@bassberry.com)

**Nesrin Garan Tift**  
(615) 742-7903  
[ntift@bassberry.com](mailto:ntift@bassberry.com)

**Leigh Walton**  
(615) 742-6201  
[lwalton@bassberry.com](mailto:lwalton@bassberry.com)

**Elizabeth S. Warren**  
(615) 742-7719  
[ewarren@bassberry.com](mailto:ewarren@bassberry.com)

**Douglas M. Wolford**  
(615) 742-7917  
[dwolford@bassberry.com](mailto:dwolford@bassberry.com)

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