



## Safety Net Hospitals for Pharmaceutical Access

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### **Maine Implementation of Federal NDC Reporting Requirements Applicable to Physician-Administered Drugs Used in Hospital Outpatient Settings: A Potential Model for Other States**

#### **Background**

On October 16, 2009, the Centers for Medicare and Medicaid Services (CMS) sent a transmittal to every state Medicaid agency in the country clarifying the National Drug Code (NDC) reporting requirements applicable to hospitals billing Medicaid for infusion products, injectables, and other physician-administered drugs (PADs). In the transmittal, CMS acknowledged for the first time that states have the authority to exempt all or a subset of hospital physician-administered drugs from the NDC reporting requirements without risking the loss of federal matching funds. CMS's clarification recognized that the federal NDC reporting requirement must be read in conjunction with section 1927(j)(2) of the Social Security Act, which specifically exempts from Medicaid rebate requirements Medicaid hospitals that (1) dispense covered outpatient drugs using formulary systems and (2) bill the state at no more than the hospital's "purchasing costs as determined under the state plan." If states interpret their state plans such that states can treat all or a subset of hospital physician-administered drugs as being billed at the drug's "purchasing cost," then the drugs are no longer rebatable under Medicaid, thereby rendering them exempt from NDC reporting.

#### **Maine Approach**

The State of Maine was one of the first states to take advantage of CMS's October 2009 transmittal. The state's Medicaid agency, MaineCare, sent a December 1, 2009 letter to all hospital administrators in the state announcing that, based on the CMS transmittal, it was exempting hospitals from the NDC reporting requirements described above. MaineCare also announced that its existing prospective payment and settlement process would not have to be modified. MaineCare submitted a State plan amendment to CMS, containing the NDC reporting exemption.

MaineCare also took the extra step of seeking the approval of CMS for its proposed NDC reporting exemption, and, in a letter dated April 15, 2010, requested confirmation from CMS that the only Maine hospitals subject to the NDC reporting requirement are critical access hospitals (CAHs) not participating in the 340B program, as all other hospitals are reimbursed at below their purchasing costs as defined under the State plan. MaineCare also inquired whether non-exempt hospitals are required to report all NDCs, or only a specified "set" of NDCs that represent the bulk of Medicaid rebates.

CMS' initial, informal response to MaineCare's inquiry was not promising. In a preliminary telephone conversation, a CMS representative stated that all 340B hospitals were required to report NDCs unless they billed Medicaid at the actual acquisition cost (AAC) of their 340B drugs. As a result of this discouraging feedback, MaineCare withdrew its State plan amendment. However, on or around September 21, 2010, MaineCare received a long-awaited, official response from CMS. In its letter, CMS corrected its position and confirmed that, because the Maine State plan specifies that Maine hospitals (apart from non-340B CAHs) are reimbursed at below the hospitals' purchasing costs, these hospitals are exempt from federal NDC reporting requirements under section 1927(j)(2). CMS also stated that non-exempt hospitals must report NDCs for all single-source drugs and for at least the top 20 multiple-source

drugs, as determined by the U.S. Department of Health and Human Services.

In the wake of the favorable response from CMS regarding the application of the section 1927(j)(2) exemption to the majority of its hospitals, MaineCare will continue with its plan to exempt qualifying hospitals, including 340B hospitals, from federal NDC reporting requirements. To qualify for the exemption, these hospitals are not subject to any changes in how they bill and get paid for their 340B physician-administered drugs. Key features of the MaineCare model are summarized below.

- **Hospitals are exempt from NDC reporting** – MaineCare noted in its letter to hospital administrators that CMS allows states to exempt hospitals from NDC reporting requirements if they use drug formularies and charge Medicaid only “acquisition costs” for the drugs. Although the CMS transmittal actually uses the phrase “purchasing costs” instead of “acquisition costs,” the agency nonetheless interpreted its existing hospital cost settlement system as meeting CMS’s conditions for the NDC reporting exemption. The state will likely formalize this approach by re-submitting its State plan amendment to CMS.
- **Hospitals may continue to bill at usual and customary rates** – Many states have opted to exempt 340B hospitals from NDC reporting requirements because the primary purpose of collecting NDC information – namely to identify the drugs administered to Medicaid patients in order to request manufacturer rebates for such drugs – does not apply to 340B drugs. This is because, under federal law, manufacturers are protected from paying rebates on 340B drugs. However, some states mistakenly believe that, to meet federal requirements, the exemption is conditional upon the hospitals’ billing at AAC.<sup>1</sup> MaineCare’s decision to preserve its year-end cost-based settlement process for hospitals means that 340B hospitals are spared the hardship of having to alter how they bill Medicaid for physician-administered drugs, including billing at AAC. The state allows the hospitals to continue billing such drugs at their usual and customary non-340B rates, but then expects payment of a refund as part of an annual settlement process. In this manner, MaineCare relies on its settlement process, rather than requiring 340B hospitals to bill at AAC or to otherwise change how they bill Medicaid, to ensure that the state is not overpaying for 340B drugs.
- **340B hospitals are not required to pass their entire 340B discount to the state** – Under Maine’s unique billing and payment system for hospital physician-administered drugs, reimbursement is settled annually at approximately 84 percent of the costs reflected on the hospitals’ filed Medicare Cost reports and the hospitals are required to repay the state the difference between the costs initially billed and the final settled costs. This is an approach with which Maine hospitals are comfortable because it allows them to retain a portion of their 340B discounts on physician-administered drugs.

For non-340B CAHs, MaineCare’s letter to hospital administrators imparted less favorable news. After describing the state’s position that hospitals are exempt from federal NDC reporting requirements, MaineCare explained that NDC reporting is still required as a matter of state law. The letter cited Maine Public Law 2009, Chapter 213 – the FY 2009-2011 state budget – as requiring the state Medicaid agency “to affect savings by collecting allowed manufacturer rebates on physician-administered drugs.” Nevertheless, MaineCare recognized the administrative difficulty that all hospital systems have in tracking the NDCs of physician-administered drugs. Accordingly, the agency initially limited the drugs

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<sup>1</sup> This misunderstanding is likely the result of a 1993 guidance issued by the Health Resources and Services Administration (HRSA) requiring 340B providers to bill Medicaid at AAC. In 2000, however, HRSA retreated from this AAC billing standard and instead directed covered entities to follow state reimbursement policies for applicable billing limits.

for which NDCs must be reported under state law to a list of 60, which are those single source drugs that represent the bulk of Medicaid rebates. The state is now considering what drugs will be subject to NDC reporting for non-exempt hospitals in light of the CMS response of September 21, 2010,

### **A Model for Other States**

The result of MaineCare's response to the CMS transmittal was that 340B hospitals in Maine would not have to change their billing systems and are relieved of the administrative burdens and costs associated with submitting NDCs on drugs purchased through the 340B program. Moreover, rather than passing all of their 340B discounts to the state by billing at actual acquisition cost, 340B hospitals are subject to an annual settlement process that requires them to refund only a portion of their 340B savings to the state. Maine's approach highlights how states can best comply with federal NDC reporting requirements while simultaneously relieving 340B hospitals from the potential regulatory burden of reporting NDCs and preserving in part the benefit of participating in the 340B program.

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