Section 6002 of the Federal Deficit Reduction Act of 2005 (DRA) requires State Medicaid agencies to collect information on certain physician-administered drugs to secure Medicaid rebates from drug manufacturers. To comply with the DRA and collect the rebates, State Medicaid agencies must require providers to include National Drug Codes (NDCs) on every claim involving the relevant physician-administered drugs. If State Medicaid agencies fail to do so, they will lose federal financial participation.

Medi-Cal, California’s Medicaid program, obtained a temporary hardship waiver from the Center for Medicare and Medicaid Services (CMS) that effectively granted California providers until April 1, 2009 to comply with the NDC billing requirement. Claims submitted without NDCs after that date will be denied. There are no hardship exemptions for individual providers, even if the provider’s cost of implementing the NDC billing requirement is exorbitant.

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NDCs Defined

An NDC is a unique number that identifies a specific prescription drug. NDC numbers are 11 digits long, formatted in a 5-4-2 format (e.g., 12345-1234-12). The first five digits of an NDC identify the drug manufacturer.

Drugs must be billed with the actual NDC that appears on the drug container, vial, tube, or bottle from which the medication is dispensed. This is particularly important when a drug is manufactured by more than one company, because it is considered Medicaid fraud to bill for one manufacturer’s product but dispense another manufacturer’s product. Furthermore, using the incorrect NDC prevents Medi-Cal from collecting a rebate on the erroneously billed drug, because the manufacturer listed on the claim will not have a record of selling the drugs associated with that NDC to the billing provider.

Drugs Subject to the Billing Requirement

The NDC billing requirement applies to all single-source physician-administered drugs and the top twenty physician-administered multiple-source drugs with the highest dollar value.

Congress chose to require NDCs for physician-administered drugs because these drugs were historically billed without NDCs, which prevented states from collecting rebates.

According to Medi-Cal, the definition of physician-administered drugs include all outpatient prescription drugs covered by Medi-Cal, manufactured by an authorized manufacturer, provided or administered to a recipient, and billed by a provider other than a pharmacy.

This definition includes drugs billed by physician’s offices, clinics, and hospitals for outpatient services, regardless of the method of administration. It includes drugs that are billed separately as covered outpatient drugs, but not drugs that are billed globally as part of another service. For example, drugs billed as part of an emergency room service need not be billed with an NDC, because...
the cost of the drug is bundled in with the cost of the service. However, drugs administered incident to an emergency room service that are billed separately are covered under the rebate program and must be billed with an NDC so that the state can collect federal matching funds.11

Only those drugs manufactured by authorized manufacturers are reimbursable under Medi-Cal. Authorized manufacturers are drug manufacturers that have signed a federal rebate agreement and are participating in the federal Medicaid rebate program. The list of manufacturers participating in the rebate program changes periodically and is available in Part 2 of the Medi-Cal Pharmacy Manual under the Section entitled, “Drugs: Contract Drugs List Part 5 - Authorized Manufacturer Labeler Codes.”12

**Implementation Challenges**

By April 1, 2009, Medi-Cal providers must bill using the correct NDC in conjunction with the appropriate HCPCS Level I, II, or III code.13 Medi-Cal will use the HCPCS code to determine claim reimbursement and will use the NDC information to process drug rebates. If a provider uses or mixes multiple drugs for a single HCPCS procedure, all of the NDCs should be included on the claim, and the HCPCS code should be repeated next to each NDC.

CMS received multiple comments concerning the logistical difficulties facing providers and states trying to implement the NDC billing requirement. CMS acknowledged that there would be operational difficulties and that providers would have to modify their dispensing and billing systems, but CMS stated that there was no reason to believe that these difficulties would result in reduced access to care.14 CMS stated, “the burden associated with this requirement is the time it would take for a physician’s office, hospital outpatient department or other entity... to include the NDC on claims submitted to the state.... We believe this would take approximately 15 seconds per claim.”15 Based on wage and benefits estimates for office and administrative services, and on information from the American Hospital Association, CMS estimated that the per claim cost would be under 9 cents and that each hospital would have to spend up to $230,000 to make the required systems modifications.16

Recent provider experiences have shown that CMS’ estimates are unrealistically low. According to numerous providers, the time and expense associated with implementing the NDC requirement has already surpassed CMS estimates several times over. For example, one large hospital chain estimates that it will cost $12 to $15 per claim to transition to a billing system that captures NDCs.17 Even though Medi-Cal began accepting claims with NDCs on September 1, 2008, only two percent of Medi-Cal providers are currently able to submit claims with NDCs.18

Providers still struggling to meet the NDC requirement face a litany of difficulties. Providers relying on vendor-supported billing software are slowly discovering that their vendors may not be able to meet the April 1, 2009 deadline. These providers must either develop a process for manually capturing NDCs while the vendor works on updating the software, or find a new vendor and implement an entirely new billing system. Manually collecting NDCs is time-consuming and resource-intensive, because it depends upon a reliable crosswalk between the hospital’s Charge Description Master and NDCs. A crosswalk is difficult to develop because each entry in the CDM corresponds to multiple NDCs. Manual billing is further complicated by the unavailability of an up-to-date database of NDC numbers from Medi-Cal or CMS.

Even providers with updated billing software must now train their Information Technology and Billing departments to use the new software. All new software must be tested to ensure that it complies with HIPAA and other privacy laws.

All affected providers must also develop and implement protocols for recording the NDC number when a physician-administered drug is dispensed, and ensuring that this information is passed from a pharmacist or physician to the billing department. Clinical and billing staff must be trained to comply with these protocols.

Providers that are not equipped to bill with NDCs by April 1 will see their claims for outpatient prescription drugs denied by Medi-Cal. Given the implementation challenges outlined above, providers should immediately dedicate sufficient resources to comply with the NDC requirement by April 1.
Legal Challenge Mounted

On August 21, 2008, a coalition of safety net hospitals filed a lawsuit challenging the NDC billing requirements. In *University Medical Center of Southern Nevada vs. Leavitt*, 1:08-cv-01456-CKK, the plaintiffs have argued, among other things, that Section 1972(j)(2) of the Social Security Act excludes most hospital providers — including 340B hospitals, which are discussed below — from the rebate program and the NDC billing requirement, because it contains an exemption for hospitals that bill Medi-Cal no more than the actual acquisition cost of the drug, as determined under the State Plan. The State Plan allows reimbursement at “estimated acquisition cost.” As of the publication of this article, the parties are awaiting a decision on the government’s motion to dismiss.

Impact on 340B Providers

Section 340B of the Public Health Services Act requires drug manufacturers to sign a pricing agreement with HHS stipulating that they will sell drugs to certain “covered entities” at or below a

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specified maximum ceiling price. Covered entities include federal grantees, federally-qualified health centers, some family planning projects, and some disproportionate share hospitals. Through the 340B program, covered entities realize significant savings on drugs, but may charge Medi-Cal no more than the actual acquisition cost of a drug plus a reasonable dispensing or administration fee. To avoid an illegal duplicate discount - first, when the manufacturer sells the drug at a discount to the provider, and second, when Medi-Cal receives the claim from the provider and seeks a rebate on the same drug from the same manufacturer — Medi-Cal must exclude claims for 340B drugs from the collection of rebates.

Until recently, most 340B providers avoided the prohibition on duplicate discounts by simply omitting the NDC from claims for 340B drugs, because Medi-Cal could not collect a rebate without an NDC. However, the DRA invalidated this approach by requiring the submission of NDCs on all claims for physician-administered drugs. For this reason, some 340B providers are arguing that the DRA undermines the purpose of the 340B program, which involves excluding certain outpatient drugs from the rebate process altogether, and therefore the NDC reporting requirement is completely unnecessary and unreasonably burdensome for 340B providers. This argument is among those in front of the district court in University Medical Center of Southern Nevada, discussed above.

Until a court decides otherwise, 340B providers in California should plan to comply with the DRA by April 1, 2009. According to Medi-Cal, providers should identify 340B outpatient drugs by billing those claims with NDC codes and a “UD” modifier. This modifier will notify Medi-Cal not to seek a rebate on the drug. To bill with a UD modifier, 340B providers must develop protocols for tracking when 340B drugs are dispensed and which patients receive them. This may involve generating a completely separate Charge Description Master for 340B drugs and maintaining separate inventories of 340B drugs and non-340B drugs.

The administrative difficulties involved in billing with the UD modifier have prompted some California 340B entities to examine their choices under the new NDC scheme. The NDC requirement effectively leaves 340B providers dispensing physician-administered drugs with three less-than-ideal choices. First, they can purchase the drug at the 340B discounted prices and bill at actual acquisition cost with the UD modifier. This choice allows providers to take advantage of the low 340B price, but requires the development of the tracking protocols discussed above.

Second, they can purchase the drug outside of the 340B program and bill it with an NDC but without the UD modifier, the same way that any other physician-administered drug would be billed. This option is not ideal because, although it allows Medi-Cal to collect a rebate, it prevents providers from taking advantage of the low 340B prices.

Third, they can opt not to bill Medicaid for the drugs at all. Although this option permits providers to purchase drugs at 340B prices, and to dispense the drugs without the use of tracking protocols, it is hardly ideal for providers or Medi-Cal. This approach prevents providers from receiving reimbursement for any physician-administered drugs, and it prevents Medi-Cal from collecting rebates from the manufacturers.

Conclusion

Many California providers are not prepared to meet the April 1, 2009 deadline for NDC billing established by Medi-Cal. Some providers do not know which billing software fields must be updated, how to manually capture NDC numbers so that physician-administered drugs can be billed correctly, or how dispensing machines must be reconfigured to show the NDC number when a drug is dispensed or a cocktail treatment is prepared. Providers entering into new vendor agreements may not have assessed whether the new vendors can comply with HIPAA or California privacy laws. Providers with updated software, dispensing protocols, and billing policies may need guidance about implementing these new tools so as to avoid an interruption in payments.

If you would like to discuss how you can prepare your facility to meet the April 1, 2009 deadline, or any of the topics discussed above, please contact Lloyd Bookman or Abigail Wong in Los Angeles at 310.551.8111, Mark Reagan in San Francisco at 415.875.8500, or Mark Johnson in San Diego at 619.744.7301.
Resources


Specific billing instructions: http://files.medi-cal.ca.gov/pubsdoco/ndc/articles/ndc_9630.asp.

Online tutorials form CMS 1500 and UB-04: http://files.medi-cal.ca.gov/pubsdoco/ndc/articles/ndc_9630.asp.

Medi-Cal Telephone Service Center: (800) 541-5555

Provider Manuals: Part 2, Physician-Assisted Drugs: NDC


1 Section 6002 of the DRA amended Section 1927(a)(7) of the Social Security Act and is now codified at 42 U.S.C. § 1396r-8(a)(7).


3 42 C.F.R. § 447.520(a).

4 California’s hardship waiver extended to April 1, 2008, meaning that Medi-Cal has already been out of compliance with the DRA for nearly one year.

5 NDCs with fewer than 11 digits should be converted to 11 digits by adding leading zeros, so that 12-34-5 becomes 00012-0034-05.

6 http://files.medi-cal.ca.gov/pubsdoco/ndc/articles/ndc_9630.asp.


A single source drug is defined as “a covered outpatient drug which is produced or distributed under an original new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.” 42 U.S.C. § 1396r-8(k)(7)(A)(iv).

A multiple source drug is defined as “a covered outpatient drug...for which there is at least 1 other drug product which— (I) is rated as therapeutically equivalent (under the Food and Drug Administration’s most recent publication of “Approved Drug Products with Therapeutic Equivalence Evaluations”), (II) ...is pharmaceutically equivalent and bioequivalent... [and] (III) is sold or marketed in the State during the period.” 42 U.S.C. § 1396r-8(k)(7)(A)(i).


9 http://files.medi-cal.ca.gov/pubsdoco/ndc/articles/ndc_9630.asp. The term “physician administered drug” is not defined in the DRA or in the implementing federal regulations. See 72 Fed. Reg. at 39218.

10 http://files.medi-cal.ca.gov/pubsdoco/ndc/articles/ndc_9630.asp.


12 The list of authorized manufacturers is available through the following link: http://files.medi-cal.ca.gov/pubsdoco/manual/ man_query.asp?w Search=(%23filename+drugscdl*.doc+OR+%23filename+drugscdl*.zip)&wFLogo=Contract+Drugs+List&wFLogoH=52&wFLogoW=516&wAlt=Contr act+Drugs+List&wPath=N.


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<tr>
<td>March 14</td>
<td>CAPSES Annual Conference, Long Beach</td>
<td>Linda Kollar speaks on <em>Restraints and Seclusion: the Legal Perspective.</em></td>
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<tr>
<td>25-27</td>
<td>AHLA Institute on Medicare and Medicaid Payment Issues, Baltimore</td>
<td>John Hellow provides <em>Medicare Litigation Update</em> and Byron Gross presents <em>Medicaid Litigation Update</em>. Lloyd Bookman presents <em>PRRB Update</em>.</td>
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<td>27</td>
<td>HFMA Road Show - NCA/Nevada Chapter, Reno</td>
<td>Stephen Phillips and Michael Dubin speak on <em>Privacy/HIPAA Legislation.</em></td>
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<tr>
<td>29-31</td>
<td>CAHF March Convention, Sacramento</td>
<td>Scott Kiepen and Blake Jones present <em>Meal, Rest Period and Overtime Law - Compliance Pitfalls &amp; Structuring Operations to Avoid Class Action Law Suits.</em></td>
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<td>May 14</td>
<td>ABA National Institute on Health Care Fraud, Phoenix</td>
<td>Patric Hooper speaks on <em>State Enforcement and Medicaid Fraud</em></td>
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