



March 16, 2009

### Best Price Nominal Sales Exemption Expanded

Section 221 of the March 12, 2009, federal omnibus spending bill significantly expands the number and types of entities to which Best Price-excludable nominal sales of drugs and biologics may be made. The expansion applies not only to future sales, but also to sales going back to January 1, 2007.

Section 6001(d)(2) of the Deficit Reduction Act of 2005 limited to four the types of entities eligible for the nominal sales exemption: 340B covered entities, intermediate care facilities for the mentally retarded, state owned or operated nursing homes and other safety net providers as defined by the HHS Secretary. In the final AMP rule the Secretary declined to define or implement the fourth category. Until last week, therefore, manufacturers could only exempt from Best Price nominal sales to the first three types of providers.

Last week's legislation adds to the Medicaid drug rebate statute two new categories of entities eligible for the nominal sales exemption:

“(IV) An entity that -- (aa) is described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of such Act or is State-owned or operated; and (bb) would be a covered entity described in section 340(B)(a)(4) of the Public Health Service Act insofar as the entity provides the same type of services to the same type of populations as a covered entity described in such section provides, but does not receive funding under a provision of law referred to in such section;

and

(V) A public or nonprofit entity, or an entity based at an institution of higher learning whose primary purpose is to provide health care services to students of that institution, that provides a service or services described under section 1001(a) of the Public Health Service Act, 42 U.S.C. §300.”

*Amending 42 U.S.C. §1396r-8(c)(1)(D).*

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## FDA/Healthcare Practice Group

Category IV Best Price exempted entities are 501(c)(3) tax exempt organizations that provide the “same type of services” to the “same type of populations” as a 340B covered entity, but that do not receive the federal funding necessary to qualify as 340B covered entities. The statute does not specify how closely aligned the services and the populations of the Category IV entities must be to those of a 340B covered entity to qualify for the nominal sales exemption.

Category V Best Price exempted entities are public or nonprofit family planning clinics, including university health centers that provide family planning services.

Neither category is described in the statute with sufficient specificity to give manufacturers absolute confidence as to which entities are covered and which are not.<sup>1</sup> Nor are government registries or other lists of qualified entities contemplated by the statute. Manufacturers should therefore take care to establish a reasonable process and record of diligence to determine that an entity claiming eligibility under one of these categories does in fact meet the criteria set out in the statute. Nominal sales to non-qualified entities are not exempt from Best Price, and the mistaken extension of nominal pricing to any such entity could have significant Medicaid drug rebate implications.

The expanded set of Best Price nominal sales exempted entities is to be applied retroactively back to the date on which the provisions of the Deficit Reduction Act became effective: January 1, 2007. Therefore, manufacturers should review their Best Price determinations back to 1Q07, exclude all sales to Category IV and V entities made at less than 10% of the contemporaneous quarter’s AMP (to the extent any such sales exist), and restate Best Price as necessary.

Note that this amendment explicitly expands the nominal sales exemption as to Best Price only. It does not, by its terms, expand the exemption to the calculation of AMP. CMS has indicated that it believes nominal sales exempted from Best Price should not be included in AMP (*see* 71 F.R. 39206). At some point in the future, CMS may revise the nominal sales exemption for AMP (*see* 42 C.F.R. §447.504(g)(4)) to include these additional categories. Without further guidance from CMS, however, calculation of AMP should continue to exclude only those nominal sales to 340B covered entities, ICF/MRs and state owned or operated nursing homes.

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<sup>1</sup> By contrast, drug makers can reasonably rely on the web-based Health Resources and Services Act list of qualified 340B covered entities (<http://opanel.hrsa.gov/opa/CE/CEExtract.aspx>) to exclude from Best Price nominal sales to Category I purchasers.