Hospital Group Wants to Expand Section 340B Drug Purchase Program

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The report issued by the Government Accountability Office (GAO) on September 23 regarding the Section 340B Drug Discount Program hit the streets at what could be considered a critical moment. Section 340B allows about one-third of the nation’s hospitals to buy drugs at discounted prices for outpatient pharmacies. The GAO’s drug-pricing report presents the program as akin to the “Wild West,” where pretty much anything goes. The Office of Pharmacy Affairs (OPA), which runs Section 340B out of the U.S. Department of Health and Human Services, comes across as incapable of providing oversight for both hospital drug purchases and drug manufacturer price charges.

Rep. Henry Waxman (D-Calif.), the top Democrat on the House Energy and Commerce Committee and a political benefactor of 340B, says the GAO report shows that the program is meeting its intended purpose of helping to reduce costs and improve services at safety-net hospitals and clinics.

“However, I am concerned by GAO’s findings that HRSA’s program oversight is inadequate,” he said, referring to the Health Resources and Services Administration, the division that houses the OPA.

“The agency needs to do a better job of making sure that drug manufacturers and program participants are providing appropriate discounts and meeting the law’s requirements,” he added.

On a macro level, the GAO report makes it clear that 340B can either save or cost Medicaid and Medicare money, depending on how well it is run and on how its guidelines (including some key ones now in flux) are written. That is an important point, because Congress is deciding, via its so-called Super Committee, how much to cut from Medicare or Medicaid as one way to reduce the federal deficit.

Theoretically, Congress could decide to expand the 340B program. For example, it could also allow hospitals to buy 340B drugs through inpatient pharmacies, an expansion that was seriously considered during the debate over the Patient Protection and Affordable Care Act (PPACA). However, that idea was dropped from the final bill because of opposition from brand-name drug companies. An expansion to inpatient pharmacies could, according to how it is done, save considerable money for state Medicaid programs—and hence the federal government, which contributes about 40% of a state’s Medicaid funding.

So far, the only preliminary action taken by Congress concerning the Section 340B program involves the annual appropriation for the OPA. The GAO report emphasized that the OPA is underfunded and is unable to perform necessary audits to ensure that (1) hospitals are providing 340B drugs only to those who are eligible and (2) pharmaceutical companies are discounting their drugs as deeply as they should be and are making them available in adequate quantities.

The initial actions taken by the House and Senate Appropriations Committees regarding an OPA budget for fiscal year 2012 go in opposite directions. The Senate bill keeps the OPA budget for fiscal year 2012, which started October 1, at $4.48 million. It assesses a user fee on drug manufacturers that participate in the program, a step that would raise $5 million in additional funds for the OPA. The House bill cuts the OPA budget to $2.21 million and omits the user fee.

Neither appropriations bill for 2012 addresses whether 340B should be expanded to inpatient pharmacies, as suggested by Rich Umbdenstock, Chief Executive Officer and President of the American Hospital Association, when he testified to the health subcommittee of the House Ways and Means Committee on September 23. He explained that this would allow the hospitals to further stretch their limited resources and relieve them of the burden of carrying two separate inventories and pricing structures for inpatient and outpatient drugs.

Theoretically, the Ways and Means Committee, in conjunction with Energy and Commerce and Senate Finance, could initiate authorizing legislation, making changes in 340B with an eye toward reducing Medicaid and Medicare costs. But that could also happen in the context of the deliberations of the Super Committee, which, under the terms of last summer’s debt ceiling agreement, must cut the federal budget by a minimum of $1.5 trillion over a period of 10 years. Because of that mandate, the Super Committee will be looking for major Medicaid and Medicare savings, some of which could be provided by expansion of the 340B program.

Will the GAO’s report lead to the strengthening and expansion of 340B, with an eye toward future Medicaid savings, or to a contraction of 340B because of its administrative deficiencies?

The GAO report was written at the behest of Senator Orrin Hatch (R-Utah), who inserted the requirement for the report in the PPACA. On September 23, Representative Fred Upton (R-Mich.), chair of House Energy and Commerce, Senator Hatch, and Senator Charles Grassley (R-Iowa) wrote to Mary Wakefield, PhD, RN, head of the HRSA, asking her to provide them with details on the number of audits the OPA had authorized since 1992, how much it spends on verifying participant eligibility, and other data on quantification of effort and funds.

“The answer is going to be ‘no, no, not much, and bupkis,’” jokes Michael Sullivan, Director of Government Relations and Policy for Wellpartner, Inc., the 340B vendor that works with hospitals.

“At least that’s the answer the committees expect. And that’s why we’d like to see OPA properly funded.”