

Expansion of Section 340B New Questions for Cancer

One of the benefits of the new healthcare reform law signed in March, allows for the nation's 11 designated cancer research centers to apply, for the first time, to the government's section 340B drug discount program. As a result of this action, a greater percentage of outpatient oncology treatment may begin to flow through hospital-community oncology joint ventures as more community physicians seek ways to access discounted drugs, improve pharmacy margins, and remain in practice.

Launched in 1992, under the Veterans Health Care Act, section 340B discounts drug costs for hospitals treating a disproportionate share of low-income Medicare and Medicaid and uninsured patients. Discounts on outpatient drugs are extended to participating institutions with an adjusted dis-

proportionate share index of at least 11.75%. The latest expansion of the program, under the Patient Protection & Affordable Care Act of 2010, means more entities will be

eligible for 340B participation, and that a greater percentage of outpatient cancer care drug expenditures will be discounted. Cancer care providers cannot use 340B to obtain discounts on inpatient drugs, though several healthcare reform bills considered this.

According to Health Resources & Services Administration (HRSA) Office of Pharmacy Affairs—who will establish the rules for cancer center eligibility—340B program participants receive discounts up to 60% below retail prices, 19% below the average Medicaid best price net of

rebates, and 51% less than average wholesale price. Currently, more than 2,650 hospitals access 340B and 78% of participants joined the program after 2004—many because of tightening pharmacy margins and a growing uninsured population.

David Bowman, HRSA spokesman, said the "Office of Pharmacy Affairs would work to implement whatever provisions Congress approves," but he could not specify on what that meant since the government had not officially completed its healthcare reform provisions at press time. Cancer centers contacted expect eligibility to be based on one of three requirements:

- A minimum 11.75% disproportionate share hospital (DSH) adjustment, which is based on a complicated formula combining Medicaid and Medicare inpatient days
- At least 30% of a center's net inpatient revenue deriving from Medicaid patients
- At least 30% of a center's net inpatient revenue deriving from state and local governments for indigent care



Dale Adams, PharmD

City of Hope Cancer Center in Duarte, CA, has a DSH adjustment above 12%. If accepted, Dale Adams, PharmD, Chief Pharmacy Officer at City of Hope, expects to shave at least \$8 million off the

Raises Stakeholders

By Bryan Cote

center's projected \$40 million in outpatient drug spend this year. City of Hope's total pharmacy spend in 2010 will be around \$70 million. Inventory costs will also decline at least 25%, Adams noted, once the center replaces its current inventory. "Given the cost savings we won't need to purchase as much in bulk," he said. City of Hope's outpatient business already has a positive margin, so 340B participation would "only help improve that," said Adams.

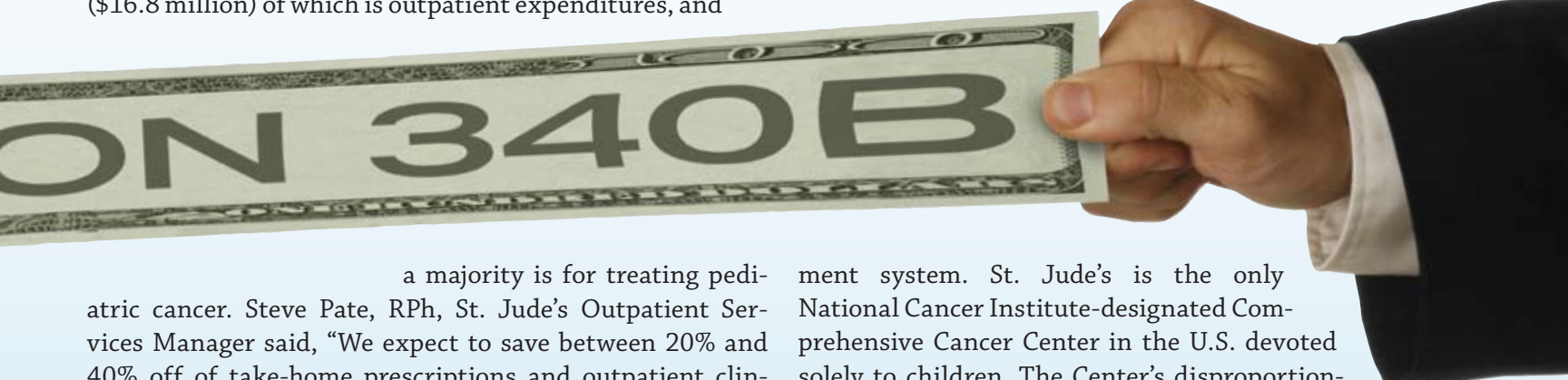
To compare, St. Jude's Children's Research Hospital in Memphis, TN, joined 340B in January of this year and spends approximately \$28 million per year on drugs—60% (\$16.8 million) of which is outpatient expenditures, and



Steve Pate, RPh

to about \$12 or \$13 million conservatively."

In general, children's hospitals were eligible for 340B as a result of a Medicare Federal Register notice issued in December '09 and later formalized in the reform law. Like the 11 designated cancer research centers, children's hospitals are excluded from Medicare's inpatient prospective pay-

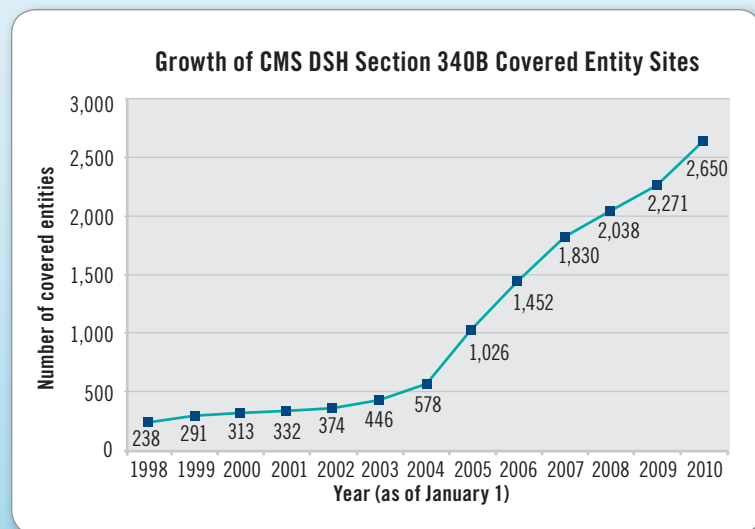


a majority is for treating pediatric cancer. Steve Pate, RPh, St. Jude's Outpatient Services Manager said, "We expect to save between 20% and 40% off of take-home prescriptions and outpatient clinic-administered drugs due to 340B, bringing us down

ment system. St. Jude's is the only National Cancer Institute-designated Comprehensive Cancer Center in the U.S. devoted solely to children. The Center's disproportionate share percentage hovers around 20%—well above the minimum 11.75% required to access 340B drug discounts. Pate does not expect St. Jude's outpatient drug spend to drop as low as \$10 million in 2010, however, partly because the list of 340B drugs eligible for rebate can change quarter to quarter.

Implementation of 340B

Adams has been following 340B for many years and used his time at Long Beach Memorial Medical Center in California to prepare for the City of Hope application. "I completed Long Beach's application in 2002," he says. "It's a tough program to get into and it's tough to administer." For example, City of Hope won't be able to pick and choose which patients receive the discounted drugs. Participating institutions may only use 340B-labeled [cont. on pg 18 >>](#)



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Expansion of Section 340B Raises New Questions for Cancer Stakeholders

drugs for outpatients and must use them for all outpatients, regardless of the patient's payer status. "We will have to do a great job tracking that these drugs are consumed by only our outpatient population," said Adams.

Almost all oncology products used in the outpatient setting are eligible for discounts, except orphan drugs which remain excluded from the 340B program despite initial legislation that called for discounts on these rare disease treatments. "This is a major victory for oncology products focused on rare cancers," said Caleb DesRosiers, MPA, JD, a health policy advisor with HillCo Health. This may lead more cancer centers to conduct orphan drug research, he thought, since the FDA now provides millions in incentives for research, tax credits, and additional patent exclusivity under the Orphan Drug Act.



Caleb DesRosiers, MPA, JD

Inpatient drugs were at one point in the health reform debate considered for 340B inclusion but lawmakers eventually decided to keep them out of the program.

When City of Hope will ultimately qualify is unclear. The Patient Protection & Affordable Care Act allows the nation's cancer centers to retroactively access 340B prices as of January 1, 2010, but to do so these centers can-

The 11 Comprehensive Cancer Centers Now Eligible for Section 340B

These comprehensive cancer centers are now eligible for the first time to apply to the 340B government drug discount program as a result of the healthcare reform law. All 11 centers are reimbursed differently than Medicare's prospective payment system.

- Arthur James Cancer Hospital
- City of Hope Cancer Center
- Dana Farber Cancer Institute
- Fox Chase Cancer Center
- Lee Moffitt Cancer Center
- Norris Cotton Cancer Center
- M.D. Anderson Cancer Center
- Memorial Sloan Kettering
- Roswell Park Cancer Institute
- Seattle Cancer Care Alliance
- Sylvester Comprehensive Cancer Center

not use a GPO for outpatient drug purchases. City of Hope had not yet stopped using its GPO, AmerisourceBergen, at the time of its application whereas St. Jude's had stopped using its GPO, McKesson, for outpatient purchases.

As the 11 designated cancer centers consider moving into 340B, they may need to consider the effect on their technology transfer business. Cancer centers and hospitals that license their molecules to biopharmaceutical manufacturers to bring medicines to market in exchange for royalty payments may not fully understand the impact of a 340B designation. If a center owns and licenses its molecules to a biopharmaceutical company, HillCo's DesRosiers warns royalty payments will suffer as sales decline overall. The technology transfer departments do not typically engage with a cancer center's reimbursement office, so, DesRosiers believes, "you potentially have decisions being made without all the facts at hand." He advised that the two offices should sit down before that 340B application is submitted. City of Hope's Adams was unsure of the impact on the center's technology transfer business.

Community Oncology Impact

Community oncologists are somewhat surprised by the recent effort to expand more discounts to hospitals through the 340B program. OBR surveyed 35 practices from 21 cities to understand their views, and most believe the expansion—while likely necessary to help cancer centers and community hospitals improve access and financial health—reverses recent government efforts to trim drug margins and shifts more cancer care back toward larger, outpatient centers.

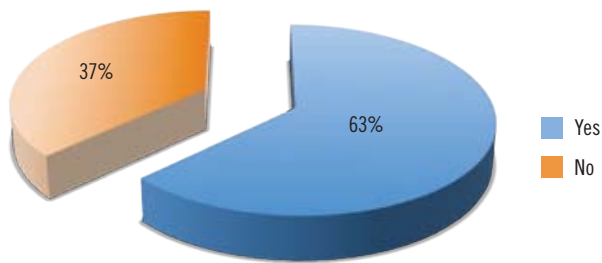
"There seem to be conflicting policies," says Mark Stanton, MD, an oncologist from the Albany, NY, area. "Managed care plans continue to push down cancer drug margins, but this 340B expansion will increase margins for more of the larger, hospital entities...it's an interesting mind game."



Bruce Cutter, MD

Bruce Cutter, MD, of Cancer Care Northwest in Spokane, WA, agrees. "Seems like hospitals get a deal here and we don't, even if we have a large number of indigent." Cutter says the law seems to do the exact opposite of government

Will 340B Expansion Lead to More Hospital-Community Oncology Joint Ventures?



N=35 community oncologists

efforts to force oncology practices to change their model. “If I were in City of Hope’s backyard I’d be upset,” said Cutter.

A majority of the 35 practices surveyed said 340B’s expansion may force more community oncologists to become employed by hospitals, though only 17% (6/35) said they are considering a move. This would follow a recent oncology trend of hospitals trying to acquire oncology groups. “We joined Hartford Hospital in 2008,” says Ramon Jimenez, MD, a pancreatic cancer surgeon at Hartford Hospital. “The reimbursement environment forced us to, and I wouldn’t be surprised if more of this happens in markets where hospitals become 340B eligible.”

Additionally, 63% (22/35) surveyed said they expect 340B expansion could lead to more hospital-oncology group joint ventures, while 82% of these 22 are concerned that these arrangements may provide an unfair economic climate for the independent community oncology group. “At first sniff, if a group partners with a 340B hospital as a way to utilize and leverage their purchasing power I’m not sure that this is in line with the intent of the original statute,” said Cutter.

Matt Farber, Director of Provider Economics & Public Policy at the Association of Community Cancer Centers (ACCC), confirms that a number of oncology groups have complained recently about doctors entering into potentially questionable joint ventures with 340B hospitals. “These haven’t been calls to applaud these arrangements, I can tell you that,” said Farber. “Groups are questioning whether these arrangements follow the intent of 340B.”

Some community oncologists surveyed said they understand the “lure for practices in tough shape” and those who miss the “high drug margins from the pre-ASP days” to merge with a larger institution; but as 340B expands, community oncologists in markets with joint ventures are less likely to be so sympathetic.

More than one-third of those surveyed (13/35) are aware of at least one 340B hospital in their market that has entered into some type of arrangement with a local oncology group. But there may be potential for “unintentional abuse” occurring with the program. According to one practice administrator, who wished to remain anonymous, practices partner with 340B hospitals, which ultimately give them better margins on drugs than other groups in their market. Nine respondents agreed that some abuse is bound to occur given the economic climate and variety of joint venture models available.

Cutter is less concerned about the ethics and more so about the model itself. “We’ve done a good job shifting from living on drug margins to a more balanced model based on quality that the health plans are finally starting to embrace,” he said. “Having lived through the early ‘90s when hospitals acquired practices, I’m not sure that these arrangements will work...it seems short-sighted to jump into one of these.”

Interestingly, 77% (27/35) of the oncologists surveyed do not have a problem with children’s hospitals and comprehensive cancer centers accessing 340B, if eligible; however, almost all of them said community oncologists should also receive access to discounts if they treat a disproportionate share of indigent patients.

“I wouldn’t disagree,” said City of Hope’s Adams. “Maybe the government can help community oncologists if the practice has a population with a high enough number of indigent by joining a purchasing program or 340B.”

Reimbursement Outlook for 340B

While 340B may give some cancer centers and hospitals advantage over community physicians for a few drugs, according to Scott Smith, the oncology service line director at Forrest General Cancer Center, Hattiesburg, MI, “physicians have control over which patients to send to the hospital.” Forrest General Cancer Center is part of a 512-bed county hospital and Smith believes, “basi- [cont. on pg 20 >>](#)

Expansion of Section 340B Raises New Questions for Cancer Stakeholders

cally, the physicians keep the patients with profitable payers and send whoever else to the hospital. CMS has to equalize the payment systems between physicians and hospitals so that patients are not steered in either direction purely for financial reasons.”

Smith thinks ASP+ 4%—the hospital reimbursement rate for all drugs under Medicare’s Outpatient Prospective Payment System—does not adequately cover hospital costs for drugs even with the 340B pricing.

Revising the reimbursement method for 340B providers is among the items the government’s Office of Inspector General (OIG) is investigating. Hospitals are being reimbursed differently for the same oncology products and the OIG is planning an audit this year to address this. All hospital outpatient drugs are supposed to be reimbursed at ASP+ 4%, but the OIG has found that many disproportionate share hospitals (DSH) in the 340B program are paying lower prices to acquire outpatient drugs but are receiving more than ASP+ 4% for administering them. Some non-DSH providers are reimbursed less for the same products and the government is seeking to fix the discrepancy.

“Even though 340B drugs are not included in the ASP calculation they are included in the ASP plus calculation and so these discounted drugs are, in effect, lowering the potential reimbursement to some hospitals,” said Farber. “That’s our major complaint here, because if you took 340B drugs out of the ASP plus calculation, you’d be at ASP plus 7% to 8%.” A Government Accountability Office report on the investigation is due in 2011.

Final Thoughts

In the short-term, 340B’s expansion at least means an increase in the number of hospitals and comprehensive cancer centers accessing discounts and lowering their overall outpatient drug spend by 20% or more. This may further fuel an increase in more joint ventures and employment contracts between hospitals and community oncologists though it may also ignite greater policy discussion about the business and legal implications of these arrangements. From a business perspective, this means more of the cancer treatment dollar will be discounted and more of it may flow through the large, comprehensive outpatient centers. Efficacy, safety and outcomes are still the key factors driving cancer treatment choice at 340B institutions, said Talar Glover, MS, RN, of the Harris County Hospital District in Houston, TX, a 340B hospital. Inter-

estingly, while most community oncologists we surveyed were clearly skeptical about the recent policy, most see 340B’s expansion as at least important for the 11 centers to keep patients away from hospital-based cancer clinics. As one physician said, “I think that cancer care and specifically oncologic drug therapy will move towards the outpatient cancer centers to give patients a one-stop shop for care—and I think this 340B change helps do more of that.”

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Section 340B Implementation Background

To access discounts on outpatient drugs through 340B, hospitals must:

- Develop a system to track outpatients
- Maintain the DSH eligibility percentage
- Stop using a GPO for outpatient drugs
- Develop two pharmacy chargemasters for billing 340B drugs separately
- Identify where outpatients receive drugs, the type of encounter, and the patient

Managing 340B is somewhat easier for a hospital like St. Jude’s since all of its outpatients are “our own and not seeing other doctors,” said Steve Pate, RPh, Outpatient Pharmacy Manager. Strict billing requirements have led some hospitals, according to Pate, to decline 340B participation. Several vendors provide split billing software to help 340B hospitals manage their billing; drugs that don’t qualify for a 340B discount can be purchased through the hospital’s GPO.

>>OBR DAILY NEWS FLASHES

HHS Secretary Kathleen Sebelius told Wellpoint to stop dropping health insurance coverage for women with breast cancer, after Reuters reported that the insurance carrier was targeting those women in an attempt to cancel policies. (HHS Press Release, 4/23/10)

Some of the biggest news from AACR’s April Annual Meeting: The BATTLE lung cancer trial which set a path for bringing personalized medicine and biomarkers into the care of lung-cancer patients. (Wall Street Journal, 4/19/10)

In more distressing news about cancer clinical trials, an ASCO survey found that one-third of NCI Cooperative Group Sites plan to limit participation in federally funded clinical trials due to inadequate per-case reimbursement. (ASCO Press Release, 4/15/10)