Many hospital pharmacy directors around the country are rubbing their hands together hungrily, ready to dig in to the federal 340B Drug Pricing Program as if it were a Thanksgiving Day feast. The program provides federally designated health clinics and so-called safety net hospitals access to deeply discounted drug prices.

Two recent developments make the program, which has been around since 1992, an even juicier repast. First, the Health Care Reform Bill, known as the Patient Protection and Affordable Care Act (PPACA), which Congress passed in March 2010, contained first-time access to discounted 340B drugs for five new categories of hospitals:

- critical access hospitals
- sole community hospitals
- rural referral centers
- free-standing children’s hospitals
- free-standing cancer hospitals

The Health Resources and Services Agency (HRSA), which administers Section 340B, held an expedited sign-up period for those hospitals from August 2 to September 27, 2010. Hospitals that didn’t get their applications in during that period must wait until January 1, 2011, to apply.

HRSA Administrator Mary Wakefield, PhD, RN, says:

We estimate that as many as 1,500 additional hospitals may now be eligible for discounted medications through the Affordable Care Act. In total, we believe the number of sites participating in the 340B program will rise from more than 14,000 to nearly 20,000 when you also factor in clinics and health centers that will be eligible.

Both newcomers and veteran participants will be able to buy larger quantities of 340B drugs, thanks to a new policy announced last March by the Office of Pharmacy Affairs (OPA) at the HRSA. The new rule allows all hospitals in the 340B program to extend sales of 340B drugs beyond their outpatient pharmacy and a limit of one retail location to numerous retail pharmacies. Hospitals, for the first time, will be allowed to sign agreements with retail pharmacy networks. The hospitals, in essence, would buy 340B drugs, stock the drugstore’s inventory with them, and then handle reimbursements when hospital patients fill prescriptions at their local drugstore.

It is important to understand that the 340B program was developed to help safety net hospitals build their profits so that they could ably serve the community. Their patients, up until now, filled prescriptions at the hospital’s outpatient pharmacy and the hospital billed the patient’s insurance company for the full price of the drug, which it obtained at a 340B price, usually 25% to 40% of the average manufacturer’s price (AMP). That differential goes into the hospital’s pocket, totaling as much as $10 million per year for some larger hospital systems.

That dab of honey on the bottom line of a safety net hospital (or federal clinic) is especially sweet these days, with public hospitals beset by state cutbacks in Medicaid funding at the same time that their uncompensated care to low-income populations has increased. Last February, the National Association of Public Hospitals and Health Systems estimated that the increase in uncompensated care costs averaged more than $2.3 million per hospital; some hospitals incurred more than $16 million in additional costs. Not all public hospitals qualify as safety net hospitals, which must exceed a certain level of Medicaid recipients as a percentage of total patients—but all safety net hospitals are public hospitals.

Patients, however, are not the prime beneficiaries of 340B; hospitals are. Typically, these safety net hospitals are owned by the state, county, or city; they are the medical care options of last resort for the working poor. Pharmaceutical companies must make all of their drugs available at 340B prices if they wish to sell those same drugs to state Medicaid programs. Medicaid and 340B prices can differ, and the latter are based on complicated formulas, made more opaque by the fact that the drug manufacturers do not have to publish their 340B prices; moreover, the OPA does not make them available to hospitals. That is changing as a result of one provision of the PPACA.

To qualify for 340B drugs, a hospital must show on its Medicare Cost Report that it serves Medicaid patients at a rate of at least 25% (even though those Medicaid patients do not qualify for 340B drugs). This is called a Medicare “disproportionate share hospital” (DSH). The DSH adjustment must actually exceed 11.75%. The hospital must also be public (owned by a city, state or county). The hospital’s outpatient pharmacy buys the discounted drugs and sells them to either Medicaid or working poor “patients”—hence the importance of this definition—for the 340B price. The hospital then bills the insurance company for the full price, pocketing the 340B discount.

Diana Bond, RPh, Director of Pharmaceutical Services at the University Medical Center of Southern Nevada (UMC), estimates that participation in the 340B drug program saves her hospital about $9 million each year. The center is smack-dab in the middle of Las Vegas, and owned by Clark County, an area served by three other hospital systems: two for-profit (Valley Health Systems with five hospitals and Hospital Corporation of America with three) and Catholic Health Care West, a not-for-profit but not a safety net hospital. UMC has 12 clinics in distant parts of far-flung Las Vegas Valley and Clark County. One clinic, two blocks from the hospital in downtown Las Vegas, has an outpatient pharmacy, as does the hospital.

Ms. Bond says, “The nine million we save annually because

Mr. Barlas is a freelance writer based in Washington, D.C.
of 340B helps underwrite the entire system, our level 1 trauma
center, neonatal level 3, the only burn unit that serves northern
ern Nevada, plus California and our transplant unit.”

The annual savings earned by UMC of Southern Nevada are
more or less typical. Andrew Lowe, PharmD, Pharmacy Director
at Arrowhead Regional Medical Center in Colton, Calif., says his
hospital “earns” $11 million per year. Those savings, pocketed
by the 800 DSHs (out of approximately 8,000 hospitals in the
U.S.) and by federally qualified health clinics currently regis-
tered in the program, help explain why critical access hospitals,
sole community hospitals, rural referral centers, and free-stand-
ing children’s and free-standing cancer hospitals, all of
which won first-time access by the PPACA, are sali-
vating at the prospect of 340B enrollment. However, chil-
dren’s hospitals and cancer hospitals that obtain
covered outpatient drugs through a group-purchasing
organization (GPO) are not eligible for partici-
pation in the expanded 340B program.

Although the 340B program smells like roses to the
hospitals and thousands of federal clinics that
were enrolled before the PPACA was passed, that
law’s opening of the door to the five new categories
of covered entities came with a few thorns attached.

In the version of the PPACA that Congress originally passed
on March 23, 2010, the 340B provision extended access to all
hospitals and contained no restrictions on drug categories
that the new entrants would have to access. But between
March 23 and March 28, Congress quickly wrote technical
amendments to the PPACA, ostensibly correcting wording
errors and confusing language—but not the substance—in
the bill it had passed just six days earlier. However, the drug
manufacturers, represented by the trade group Phar-
caceutical Research Manufacturers of America (PhRMA), and
the biotech manufacturers, represented by the Biotechnology
Industry Organization (BIO), worked overtime during that six-
day period. And presto—when the technical corrections bill
was signed by President Barack Obama, it deleted access to
inpatient pharmacies and excluded 350 orphan drugs from the
list of 340B drugs available to the five categories of newly
covered entities.

“That was an unpleasant surprise for 340B providers,” says
Ted Slafsky, Executive Director of Safety Net Hospitals for
Pharmaceutical Access.

That orphan drug exclusion may douse the interest of some
of the hospitals for which the 340B door has now swung open.
Many of those excluded agents are expensive cancer drugs.
Diana Bond says that when UMC entered the 340B program
in 1994, the pharmacy saw a drop of 75% in the cost of cancer
drugs in the first year. Without that big-ticket discount, the
nation’s 11 free-standing cancer centers in the U.S. would
think twice about entering 340B. As it happens, only one cen-
ter has a high enough DSH percentage to qualify for 340B—
the City of Hope Hospital in Duarte, Calif., near Los Angeles.

Another facility with first-time access to 340B is Enum-
claw Regional Hospital, in the state of Washington, located in the
foothills of the Cascades Mountains. This critical access hos-
pital, defined as having fewer than 25 beds, is the only hospi-
tal around for miles. Enumclaw jumped at the opportunity
to get 340B prices and was accepted by HRSA about two weeks
after applications were allowed to be submitted. It was able to
move quickly because the Franciscan Health System in the
state had been dealing with 340B with three of five hospitals
such as St. Joseph Medical Center.

Michael Bonck, RPh, Pharmacy Manager of Franciscan
Health System and chairman of the institutional review board,
and his colleagues quickly submitted an application for Enum-
claw, which was approved. The outpatient pharmacy at Enum-
claw is already contributing to the hospital’s bottom line by
saving money on drugs such as zoledronate (Reclast, Novar-
tis), the once-yearly infusion for osteoporosis. However, Enum-
claw’s outpatient pharmacy will not be able to buy
infliximab (Remicade, Centocor), for example, at
340B prices, and that hurts badly. Mr. Bonck says that
infliximab, which has an indication for Crohn’s dis-
 ease and is on the list of 350 mostly expensive drugs
not available at 340B prices to new participants,
accounts for $280,000 in annual sales at Enumclaw,
where it is primarily indicated for the treatment of
rheumatoid arthritis and Crohn’s disease.

“That is a huge value proposition loss for Enum-
claw,” he states, especially considering that inflix-
imab constitutes about 23% of the hospital’s total
drug spending in a year. That is particularly galling, he adds,
because orphan drug status is supposed to be awarded only to
drugs with small markets, and Johnson & Johnson’s (J&J’s)
Sales of infliximab, which the FDA has also approved for
ankylosing spondylitis, pediatric Crohn’s disease, ulcerative colitis,
psoriatic arthritis, and plaque psoriasis, are estimated to be
$5.45 billion per year. Mr. Bonck and others are waiting for clar-
ification from the OPA as to whether manufacturers have to
make the 350 orphan drugs available at 340B prices for non-
orphan indications.

Kassy McGourty, a spokesperson for J&J, says that inflix-
imab and several other products do have approved orphan
drug indications. She explains:

“However, the recently passed legislation poses a very com-
plicated situation. Like many health care companies, we’re re-
viewing the situation and seeking guidance from HRSA and
CMS. We hope to have a resolution in the next several weeks.”

Although orphan drugs will not be available to newly minted
340B participants, the program’s veterans have had problems
in the past getting 340B prices on clearly eligible drugs. Michael
Bonck says that patented drugs such as etoposide (Integrilin,
Schering-Plough), used in percutaneous coronary interven-
tion (PCI) procedures, and bivalirudin (Angiomax, The Medi-
cines Company), used in coronary angioplasty, are very ex-
pensive and were hard to get at 340B prices up until about
December 2009. The same situation applies to immunoglobu-
lin (from companies such as CSL Behring, Baxter, Talecris, and
Grifols), which is difficult to obtain consistently at 340B pricing.

“Companies will say there are shortages of the product,
and you have to call and call and hit the right people,” states
Mr. Bonck.

Even when a hospital pharmacist can get an expensive drug
at a 340B price, it isn’t clear that the 340B price charged by the
manufacturer is actually an accurate 340B price. The com-
pany does not have to publish 340B prices, which are propri-
etary—and as if that isn’t non-transparent enough, the OPA

Ted Slafsky

Health Care Reform and Section 340B Discounted Drugs

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Health Care Reform and Section 340B Discounted Drugs

Robert Judge, Executive Vice President and General Manager of Contract Pharmacy Services at Wellpartner, Inc., says his company collaborates with its hospital clients to set up a network of retail pharmacies strategically located to facilitate access for as many 340B-qualifying patients as possible. This process includes patient zip code mapping and linguistic compatibility to find the right neighborhood pharmacies to maximize community coverage.

Other companies around the country that offer a range of contract pharmacy administration services include SunRx, NEC Health, and Hudson Headwaters Health Solutions. In addition, retailers such as CVS, Walgreens, and Rite Aid are also scrambling to sign new 340B contracts with hospitals; however, in that latter instance, qualified hospital patients would have to use, for example, a CVS pharmacy for the hospital to be eligible for the 340B discount.

Not all contract pharmacy administrators are equal. One key thing to look for is an administrator that insures patients receiving 340B prices at retail are actually eligible. Sometimes this determination isn’t obvious, and companies such as Wellpartner have sophisticated software systems to prevent diversion to ineligible customers. Wellpartner provides detailed reports to ensure its clients’ 340B program conforms to strict federal requirements for both dispensing and replenishment. It is the 340B administrator who is responsible for replenishing drug inventories at retail locations. Inventories have to be replenished on time, and pharmacies are paid by the hospital for that replenishment, because the pharmacies typically use their own capital to buy 340B drugs.

Hospitals do have an alternative to a contract pharmacy relationship for reaching qualified patients in outlying areas who can’t get to the hospital’s outpatient pharmacy for a refill or if there is no outpatient pharmacy for the original prescription. Arrowhead Regional Medical Center in Colton, Calif., uses a company called OnTrac (formerly, California Overnight) to deliver prescriptions filled in its outpatient pharmacy to patients in outlying areas. “Split billing” is advantageous because it allows the hospital to order for both its inpatient and outpatient pharmacies and to get lower prices for both—even lower than the discounted 340B price for outpatient prescriptions—because of the combined volumes. On the other hand, the delivery cost per prescription can be higher than the administrative cost per prescription for using a contract pharmacy.

Andrew Lowe, PharmD, pharmacy director at Arrowhead, which is owned by San Bernardino County, says that his costs for filling patient refills is less expensive with OnTrac than with a contract pharmacy.

He says, “It would be more expensive to use a retail pharmacy because we would have to pay a filling fee and be responsible for the integrity of the drug distribution, including having to do audits. Diversion can be a big headache, and it doesn’t happen when we use OnTrac.”

Outpatient pharmacy use of delivery services and contract pharmacy networks to extend 340B pricing will help hospitals—both current 340B participants and the swarm of new ones—bleed off building financial pressure from their owners (i.e., cities, counties, and states) whose budgetary problems are forcing funding cutbacks at many of their public facilities, whether they be police departments or hospitals.