## IN THIS ISSUE

<table>
<thead>
<tr>
<th>Topic</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicaid Drug Rebate Increase Removed from Children’s Health Care Legislation</td>
<td>2</td>
</tr>
<tr>
<td>Settlement Between BMS and Government Includes 340B Refunds</td>
<td>3</td>
</tr>
<tr>
<td>HRSA’s Clinical Pharmacy Initiative Gains Momentum</td>
<td>4</td>
</tr>
<tr>
<td>Law Passed to Delay Tamper-Resistant Pad Requirement for Medicaid</td>
<td>5</td>
</tr>
<tr>
<td>NYC Launches Drug Discount Program to Maximize 340B Benefits</td>
<td>6</td>
</tr>
<tr>
<td>Subscription Information</td>
<td>12</td>
</tr>
</tbody>
</table>

### Government Selects Contractor to Review 340B Pricing Pilot

**Questions Raised over Effectiveness of Project**

After reviewing a number of bids from federal contractors, a North Carolina-based research institute has been selected to formally evaluate a pilot project that is intended to increase pricing transparency in the 340B program.

As the project moves forward, questions have been raised over the scope of the project and whether the contractor—RTI International—will have the necessary data to effectively evaluate the project.

RTI International, which is headquartered in Research Triangle Park, N.C., will evaluate the year-long 340B Pricing Pilot Project that began April 1. RTI was established in 1958 as the nonprofit Research Triangle Institute and has expanded to include seven U.S. offices, six international offices and two international subsidiaries. Health research is the largest field of study at RTI.

“RTI has a background in evaluation and good credentials,” says Office of Pharmacy Affairs (OPA) Director Jim Mitchell.

The request for proposal (RFP) was limited to certain government pre-approved contractors. RTI, along with the other government contractors that qualify as “Indefinite Delivery Indefinite Quantity” contractors, submitted a bid in response to the RFP issued by OPA on June 8. The technical review panel for submissions reviewed three proposals, and RTI was selected through a competitive procurement process, according to OPA. The eventual task order awarded to RTI was for $209,835.

Under the pilot, participating drug manufacturers provide pricing data to the 340B Prime Vendor Program (PVP) for comparison against the government’s calculations. Any discrepancies between OPA and manufacturer calculations are then reconciled before a master price file is distributed to wholesalers participating in the PVP. OPA and RTI are currently working to set up the evaluation process, Mitchell says.

340B covered entities and advocacy groups have argued that purchasers should have access to 340B ceiling prices to ensure they are not overcharged for 340B-discounted drugs. 340B prices are calculated based on, among other things, average manufacturer price and best price.

Marcus Farbstein, the director of government affairs at Genentech, first suggested the need for a pilot project at a 340B Coalition Conference.

“Pharmaceutical companies feel that what they have been doing is accurately continued on pg. 8
A provision that would have meant greater drug rebates for the Medicaid program and possibly increased discounts for 340B program participants was removed from legislation that would renew and expand the State Children’s Health Insurance Program (SCHIP).

SCHIP, a 10-year-old program which was set to expire on September 30, covers approximately 6 million low-income children whose families do not qualify for Medicaid. After much heated debate last month, the House and the Senate concluded negotiations on compromise legislation, which closely resembles the Senate version (H.R. 976) that passed on August 2.

The compromise bill, which passed the House on September 25 and cleared the Senate two days later, was finalized after House Democrats agreed to scale back their SCHIP expansion efforts and to drop Medicare provisions in the House bill (H.R. 3162) that was approved on August 1. The House bill would have made changes to the Medicare program, including spending cuts to the Medicare Advantage program.

Despite the broad bipartisan support for the compromise legislation, President Bush vetoed the bill that would have been financed by an increase in tobacco taxes, including a 61-cent increase in the cigarette tax. The compromise bill would have expanded the program by $35 billion over five years to $60 billion and funded coverage for about 4 million more children.

With a two-thirds majority of both the House and Senate required to override a veto, it is uncertain if Congress has enough votes to pass the current form of the bill.

The House approved the SCHIP compromise legislation by 265-159, but without enough support to override Bush’s expected veto. The bill passed in the Senate two days later by a 67-29 vote, clearing the measure for Bush. Because SCHIP was set to expire on September 30, lawmakers included a provision temporarily extending the current program in the resolution (H J Res 52) to continue spending programs into fiscal year 2008.

The more comprehensive House bill would have expanded the program by $47 billion over the next five years. Funding for the increased spending was expected from a number of sources, including requiring brand name pharmaceutical manufacturers to pay increased rebates to the Medicaid program. 340B and Medicaid stakeholders were particularly interested in Section 812 in the House bill that would have increased the applicable Medicaid drug rebate for brand name drugs by 7 percentage points, from 15.1 percent to 22.1 percent.

The prices under the 340B program are calculated using the same discount mechanism that is used to determine Medicaid rebates. 340B ceiling prices for brand name drugs are currently the lower of average manufacturer price (AMP) less 15.1 percent or Medicaid best price with additional rebates if prices rise faster than inflation. It is unclear whether 340B providers would have benefited from the rebate increase.

Democrats have included provisions in a number of bills during this session of Congress that would increase the Medicaid rebate percentage. However, the rebate increase has eventually been removed from all legislation.
340B entities are accustomed to receiving large sums of money after high-profile drug pricing settlements between pharmaceutical companies and the government. However, in the case of the recent settlement between Bristol-Myers Squibb (BMS) and the Department of Justice, entities may be disappointed with the outcome.

BMS and a former subsidiary company, Apothecon Inc., agreed to pay more than $515 million to the U.S. government and state Medicaid programs to resolve allegations of wrongdoing in the company’s drug pricing and marketing practices. While many previous cases pertaining to 340B entities revolved around allegations of overcharges related to the misreporting of the best price to the government, this settlement involves a broad array of illegal marketing and pricing practices.

Among other charges, BMS will settle allegations that it misreported its best price for the anti-depression treatment, Serzone, and has agreed to refund $124,000 to certain 340B entities. Under the provisions of the Medicaid drug rebate statute, brand name pharmaceutical manufacturers are required to report to Medicaid the lowest or best price that it charges its commercial customers. Manufacturers are also required to provide its best price to entities participating in the 340B program.

However, according to the Department of Justice, BMS knowingly omitted the lowest price at which it sold Serzone to Kaiser, a large commercial purchaser. “As a result, BMS denied the Medicaid program and certain Public Health Service entities the benefit of the lowest price in the marketplace,” according to a statement from the U.S. Attorney’s Office for the District of Massachusetts, which led the investigation.

Best price and average manufacturer price (AMP) play a key role in determining the prices that are available to participants in the 340B program and the rebates provided to state Medicaid programs. For brand name drugs, both the 340B ceiling price and the Medicaid rebate amount are calculated based on the lower of the manufacturer’s best price in the private sector or 15.1 percent off of the drugs’ AMP.

Under the settlement, BMS agreed to “present for review and audit the underlying calculations used to determine the correct price(s) for the PHS entities during the relevant time periods.”

BMS is required to pay the settlement amount to each affected entity within 60 days after the effective date of the agreement.

The government has now completed five settlements since 2003 with manufacturers that have included refunds to 340B entities. The previous refunds, which ranged from $2.5 million to $10.6 million, dwarf the recent settlement.

In addition to the best price component of the case, the settlement also alleges that BMS offered kickbacks to physicians and health care providers, such as trips and consulting fees, from 2000 to mid-2003 to entice them to prescribe the company’s drugs.

The government also accused BMS of marketing the sale of Abilify, an anti-psychotic drug, for off-label uses—including pediatric use and to treat dementia-related psychosis. The Food and Drug Administration only approved the drug for adult schizophrenia and bipolar disorder. The settlement also includes allegations of inflating prices for drugs to increase reimbursement rates.

The $515 million settlement agreement includes $328 million to the federal government, $187 million to state Medicaid programs and the $124,000 to 340B entities. The U.S. Attorney’s Office for the District of Massachusetts would not elaborate on the breakdown of the various claims beyond those outlined in the settlement.

The settlement revolves in whole or part on allegations made in six whistleblower cases in Massachusetts and one in Florida. Under the law, whistleblowers with knowledge of fraud are able to file suit on behalf of the government with the possibility of sharing in the recovery. The whistleblowers will receive approximately $50 million as their share of the federal amount and an additional share of the state settlement amount.

In a statement on BMS’ Web site, the company said that there are no criminal charges against the company, and the settlement will not affect any ongoing business. The company has entered into a five-year corporate integrity agreement with the Department of Health and Human Services Office of the Inspector General, according to the September 28 statement.
Acting on a request from Congress, the Health Resources and Services Administration (HRSA) is moving forward on plans to implement an initiative designed to promote and ensure patient safety through the use of clinical pharmacy services at 340B health care facilities. The Office of Pharmacy Affairs (OPA), which administers the 340B program, will play a central role in the initiative.

Mathematica Policy Research Inc. (MPR) was chosen, through a competitive process, to oversee the Patient Safety/Clinical Pharmacy Initiative, which will build upon previous work promoting clinical pharmacy demonstration projects at 340B community health centers. Mathematica has conducted a number of studies for OPA, including work in the area of clinical pharmacy services. OPA Director Jim Mitchell has described the project as “the most exciting initiative” he’s been associated with.

The initiative stems from a request in the Senate Appropriations Committee Report, FY 2007, for HRSA to devote more resources toward improving clinical pharmacy care. The Committee requested that HRSA submit a report “making recommendations on similar improvements that might be made to all HRSA programs in which medications play an integral role in patient care.” The report references a Mathematica study from five years ago, which the Committee asked HRSA to consider on a larger scale.

Language in the FY 2008 report, which further reiterates the need for the initiative, says the Committee “strongly encourages HRSA to continue to develop and implement cost effective clinical pharmacy programs in all of the various safety-net provider settings.”

The program aims to identify safety-net “best practice” models of patient safety and clinical pharmacy services and to transfer best practices to other safety-net providers. Congress requested that HRSA work with internal stakeholders, such as HRSA’s Center for Quality, and external stakeholders, such as representatives from the 340B Coalition, national pharmacy organizations and covered entities themselves.

According to Dennis Wagner, the deputy director of HRSA’s Center for Quality, the initiative has three main goals: (1) to improve patient safety; (2) to increase high quality, cost-effective pharmacy services; and (3) to improve health outcomes. The initiative focuses on areas where HRSA is seeking to make improvements and other areas that are seen as having the greatest impact on patient health, Wagner says.

Wagner, who will oversee the initiative, has a background in successful application of the collaborative care model and is an “expert in the area,” according to OPA Director Jim Mitchell. “Much of what we do draws on social marketing and collaborate care concepts,” he says. Wagner will work closely with the OPA staff to help design and implement the initiative.

To gather feedback, HRSA invited stakeholders, 340B Coalition members and pharmacy groups to voice their opinions at a meeting in Washington, D.C. this month. Attendees were given the opportunity to make recommendations about how to effectively implement and sustain clinical pharmacy services before HRSA submits its report to Congress. The October 4 meeting also addressed MPR’s preliminary findings from case studies with safety-net providers.

HRSA and MPR are currently trying to identify key sites where they can observe best practices in use. Researchers will observe provider activities and then allow hospital and clinic staff to participate in an observation “debriefing” session where they will present the results of their analyses. In the upcoming months, HRSA and MPR will also conduct interviews with state Medicaid directors and schools of pharmacy and further develop

continued on pg. 10
Law Passed to Delay Tamper-Resistant Pad Requirement for Medicaid

In response to complaints from state Medicaid officials, pharmacists, doctors and patient advocacy groups, a new law requiring that all non-electronic prescriptions for Medicaid be written on tamper-resistant paper by October 1 has been delayed for six months.

The law was designed to target Medicaid fraud and save the government money, but opponents say the law may have made it harder for patients to get their medications. They argue that the implementation date did not allow adequate time to prepare for the law. The relevant legislation—called the U.S. Troop Readiness, Veterans’ Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007—was signed into law on May 25.

“There hasn’t been enough information or time to adequately implement the requirement,” says Tami Eide, a pharmacist specialist with the Idaho Division of Medicaid. “I think [the law] singles out Medicaid patients, and it probably should only apply to controlled substances.”

In late September, Congress unanimously passed legislation that would delay implementation of the Medicaid tamper-resistant pad requirement until April 1, 2008. The six-month delay was introduced by Sens. Sherrod Brown (D-Ohio) and George Voinovich (R-Ohio) and passed by the Senate on September 25. Rep. Charlie Wilson (D-Ohio) introduced similar legislation in the House that passed the next day.

“The purpose of the tamper proof requirement is to combat fraud, not create chaos for patients and pharmacies,” Brown said in a statement.

On September 17, the National Association of State Medicaid Directors and more than 100 organizations sent a letter to Congressional leaders asking for a one-year delay to the rule. While they acknowledged that an August 17 letter from CMS to state Medicaid directors helped clarify what qualifies as a tamper-resistant pad, they insisted that a delay was still needed to address lingering confusion about the law and because there was insufficient time to implement the requirement.

The CMS guidance letter outlines three characteristics a prescription pad must contain by Oct. 1, 2007—now Oct. 1, 2008—to be considered tamper-resistant: “one or more industry-recognized features designed to prevent the use of counterfeit prescription forms.” A prescription pad is required to contain at least one of the three characteristics by April 1, 2008.

The tamper-resistant pad requirement would not apply to e-prescriptions, prescriptions faxed to the pharmacy, or prescriptions communicated over the phone between the pharmacy and a prescriber. The requirement also would not apply when a managed care entity pays for the prescription, according to the letter.

Burnis Breland, director of pharmacy at Columbus Regional Healthcare System in Georgia, says the new law will have a significant effect on 340B entities and patients. “We are predominately dispensing outpatient prescriptions to indigent patients and many of those are Medicaid patients,” he says.

After the law was passed in May, the state of Georgia initially delayed defining which of CMS’ characteristics would need to be implemented by October 1, Breland says. Without guidance from the state, Columbus Regional decided to print new prescription pads on tamper-resistant paper that met all three standards. “We went ahead redesigning prescription pads and took the opportunity to improve them at the same time,” he says.

Columbus Regional also communicated with different entities and facilities that use their own prescription pads to help them understand the law and how to implement it. “There are a lot of issues with this requirement, but we’re doing our best to get our hospital health system ready,” Breland says.

They also reached out to physicians and sent a summary of the rule to the medical community. It may be difficult for physicians to implement the law because many use systems that print electronically, but do not send electronically, Breland says.

“Physicians in the community are, by-and-large, not aware of the law and when they are, they are very concerned,” he says. “There is going to be a lot more confusion in the medical practices. It’s going to be problematic for patients.”

The tamper resistant requirement was intended to pay for a one-year moratorium on a government proposal to cut Medicaid spending to public hospitals. The Senate version of the Iraq/Afghanistan spending bill originally continued on pg. 10
NYC Launches Drug Discount Program to Maximize 340B Benefits

New York City has a new prescription for pharmaceutical savings. A recently launched program in the Big Apple aims to make prescription drugs more affordable for uninsured or underinsured patients in the nation’s largest city by maximizing use of the 340B program.

NYCRx, a non-profit organization founded by the New York City Department of Health and Mental Hygiene along with New York City federally qualified health centers and disproportionate share hospitals, enables patients to buy discounted prescription drugs from health center-based dispensaries and community retail pharmacies contracted with federally qualified health centers.

NYCRx Executive Director Anita Lee, along with the support of the New York City Department of Health, conceptualized the idea for the program.

According to Lee, NYCRx continues to refine and improve its service offerings to expand access to low cost pharmaceuticals for New Yorkers.

The public-private partnership that laid the foundation for the development of NYCRx received funding in September 2005. The funding came from the Healthy Community Access Program Initiative, a now defunct program funded by the Health Resources and Services Administration that provided seed money for programs that improve access to services for the uninsured.

NYCRx was introduced in April 2007 at four sites in Brooklyn and Manhattan. Since its inception, the program has expanded to an additional three sites. According to Lee, New York City has 29 federally qualified health centers and a very concentrated population of uninsured patients.

“Many eligible covered entities in New York City really haven’t taken full advantage of this wonderful program because of the many challenges associated with implementing and managing the program,” Lee says.

None of the New York City health centers own and operate an in-house pharmacy, which presents a challenge because they then have to contract with a retail pharmacy for each site. Another challenge is making sure 340B entities are maximizing the opportunity to generate revenue from the 340B program and have put in place all the procedures and monitoring mechanisms to ensure full compliance with the 340B program, Lee says.

NYCRx helps patients and pharmacies navigate through the 340B program and supports safety-net providers, such as health centers and disproportionate share hospitals, in making the most of the program.

“NYCRx is beneficial for two separate groups—underinsured and uninsured patients, and 340B covered entities,” she adds.

Harvey Lawrence, executive vice president and chief operating officer of the Brownsville Multi-Service Family Health Center in Brooklyn, says the NYCRx program “enormously” benefits uninsured patients.

“For many of them, they have to make the choice between whether they are going to fill their prescription or be able to buy groceries,” he says.

He remembers one patient who was “jumping for joy” when the price of her prescription was reduced from $100 dollars to about $30 dollars.

“The program offers prescription drugs in a way that can help those people who are uninsured and are the working poor,” he says.

NYCRx provides a community health worker at each new site for up to a month to inform staff about the program and guide patients through the 340B process.

Lawrence says the entire process is managed in a “seamless way.” NYCRx staff walked him through the nuances of the program, generated all of the reports and the necessary documentation needed to participate in the program, and coordinated with the pharmacy, he adds.

“All of those things are a real benefit because we are all very busy and to take the time out to work through all those issues would be enormously costly, not only in terms of time but also in terms of money,” he says.

Patients of covered entities do not need to apply to the program. NYCRx will work with the health center and medical staff so they have the knowledge to communicate to their patients about the program, Lee says. One of the best opportunities for patient education is when

continued on pg. 7
health center physicians are writing out prescriptions.

Savings from the NYCRx program vary by drug and range from 20 percent to 70 percent. The program works with most insurance companies. NYCRx will assist 340B covered entities to develop a mechanism to reduce copays or deductibles for patient with financial hardships.

Participants in the program also receive reminders to refill their prescriptions and various educational materials about managing illnesses and making healthy lifestyle choices.

To further reduce a patient’s out of pocket drug expenses, NYCRx will collaborate with the health center staff to determine if he or she qualifies for a manufacturer-sponsored patient assistance program (PAP), in which free drugs are donated to individuals.

PAP assistance is generally limited to patients who lack prescription drug coverage, fall below designated income levels and meet other program eligibility requirements. If a patient qualifies, NYCRx will facilitate the completion and submission of the PAP application.

“We further reduce costs to eligible uninsured patients by moving them into the patient assistance program as appropriate,” Lee says.

Nationally, the number of prescriptions purchased increased from 2.1 billion in 1994 to 3.6 billion in 2005 — a 71 percent increase, according to the Henry J. Kaiser Family Foundation. The average price for a prescription in New York is $63.34, almost $10 more than the national average.

New Yorkers spent over $13 billion on prescription drugs in 2005 alone. In addition, the state also has one of the lowest generic fill rates in the country, according to NYCRx.

---

Fourth Annual 340B Coalition Winter Conference

January 30 - February 1, 2008
Westin Long Beach
Long Beach, California

A conference designed for health care providers, the pharmaceutical industry, pharmacies, pharmacy service companies, government agencies, and other entities concerned about providing quality pharmaceutical care to low income and vulnerable populations while ensuring compliance with drug pricing laws.

Escape the winter blues and come to the newly renovated Westin Long Beach in sunny southern California for the Fourth Annual 340B Coalition Winter Conference. Keep abreast of the many changes currently taking place in the 340B program. Hear from speakers from the Office of Pharmacy Affairs, the 340B Prime Vendor Program, the 340B Coalition, industry representatives, and other experts concerned with the future of the 340B program.

Special discounts for Monitor subscribers.

Stay tuned to www.340Bconferences.org for more information.

Please contact Mike Hess at mike.hess@safetynetrx.org or (202) 552-5869 with any conference related questions.
340B Pricing Project Raises Questions

continued from pg. 1

reporting prices, but despite that, inaccurate prices do get in the system.”

The pilot, according to the RFP, “allows OPA access to data components not ordinarily available to it that manufacturers use to compute their 340B ceiling prices.” After the RFP was released, contractors had the opportunity to submit questions to HRSA by June 22.

Several of the questions submitted by prospective contractors focused on what type of pricing data would be available to the evaluator of the project. According to HRSA’s response, “OPA will provide the contractor with the necessary data—OPA will perform the price comparison on the confidential data and provide non-confidential results to the contractor—to perform the analysis of the Pilot as described in the RFP.”

Another question raised by a prospective contractor was whether or not the evaluator would have access to the HRSA calculated price. HRSA responded that the contractor would not have access or be able to independently verify the calculation.

Some pricing experts have raised concerns as to how substantive the third party evaluation will be if the evaluator only has limited access to the data. Some argue that the primary purpose of the pilot project is to allow the government to compare its 340B calculations with manufacturer prices, so RTI will not be able to evaluate the effectiveness of this comparison process directly.

“From an auditing perspective, the approach OPA is taking may be helpful to address the common pricing issue, however, by not letting the evaluator see the primary data, but rather having them look at summary tables produced by HRSA, it doesn’t meet the standards of evaluation that either the Office of the Inspector General or the Government Accountability Office would require,” says a former federal auditor in the field.

While the contractor will not have access to confidential pricing data, they can still evaluate the process OPA sets up, Mitchell says. He says sharing prices with the government may give some element of risk reduction to drug companies, but that the pharmaceutical industry is still responsible for pricing.

“I think the pilot has the high potential of resolving the vast majority of the problems that have been identified,” Mitchell says.

Some 340B entities have also expressed concern that only participants in the 340B Prime Vendor Program will have access to the pricing information. According to the RFP, “All data submitted by a manufacturer to the Program would remain confidential except for access by wholesalers and covered entities that participate in the 340B Prime Vendor program.”

Derek Robertson, the executive director of the Hemophilia Alliance that represents most of the hemophilia treatment centers in the 340B program, says most of its members are not part of the Prime Vendor program.

“Our view is that this should be open to 340B covered entities regardless of their status with the Prime Vendor,” he says. “This is a service that OPA should be providing to covered entities—they should not be linking it to joining the Prime Vendor.”

The pilot program does not interrupt the standard flow of pricing data, in which manufacturers calculate the ceiling prices and release them to the marketplace without a system of validation, but participants hope it will eventually allow for improvements in the system. Because making corrections after the prices are released to the marketplace can be time-consuming and costly, the pilot program aims to make the system more efficient by correcting pricing problems beforehand.

“We will continue to have challenges—if you run a pilot you are testing concepts, so there are always challenges,” Mitchell says. “But so far we are very satisfied [with the pilot].”

The price transparency pilot was implemented following a series of reports on the 340B program from the Health and Human Services (HHS) Office of Inspector General (OIG). A July 2006 OIG report found one in seven purchases by 340B-covered entities was above the federally mandated ceiling price. The report called for greater penalty authority for OPA to enforce compliance with Section 340B of the Public Health Service Act, which echoed previous reports in recommending that HRSA officially compare manufacturer and government price calculations to detect discrepancies.

At a December 2005 hearing, members of the House Energy and Commerce Subcommittee on Oversight and Investigations also raised concerns about transparency of manufacturer ceiling price information and OPA’s ability to monitor whether covered entities are receiving the correct prices (See December 2005 Monitor).

continued on pg. 10
**PRODUCT LIST**

### Fertility
- Pregnancy Cassette / Dipstick Test
- Pregnancy Cassette Combo Test
- Ovulation Cassette / Dipstick Test

### Infectious Diseases
- Strep A Swab Cassette Test
- Cholesterol Card Test
- Glucose Fasting Card Test
- H. Pylori Cassette Test
- Mononucleosis Cassette Test
- Fecal Occult Blood Cassette Test

### Drugs of Abuse
- DOA Single Panel Dipstick Test
- DOA 4, 5, 6, 10 Panel Dipstick Test
- DOA Single Panel Cassette Test
- DOA 2, 4, 6 Panel Cassette Test
- DOA 5, 6, 10 Panel Test Cup

### COMING SOON
- TB TEST
- HIV 1/2 TEST
- Troponin Test
- Semi-Quantitative PSA Test

### Pharmacy (OTC) Home Test Kits
- Pregnancy Test Kit
- Ovulation Test Kit
- Menopause Test Kit
- Breast Examination Pad
- Urinary Tract Infection Test
- Glucose Test Kit
- Colorectal Test Kit
- Cholesterol Test Kit
- DNA Paternity Test Kit
- Blood Alcohol Test Kit

---

Save Money With Steeply Discounted 340B PVP Prices

Order Direct: Click on Secure 340B PVP Link at earlydetect.com

www.earlydetect.com
contactus@earlydetect.com

Like a lab in box

Toll Free: 877-77-EARLY
Tel: 949-553-1127  Fax: 949-553-1160
SNHPA Job Opportunity

Director of Pharmacy and Educational Services

Safety Net Hospitals for Pharmaceutical Access (SNHPA), formerly Public Hospital Pharmacy Coalition, is an organization of over 400 public and private non-profit hospitals and health systems that participate in the Public Health Service 340B drug discount program. SNHPA was formed to increase the affordability and accessibility of pharmaceutical care for the nation’s low-income and underserved populations. SNHPA monitors, educates, and serves as an advocate on federal legislative and regulatory issues related to drug pricing and other pharmacy matters affecting safety net providers. SNHPA is dedicated to protecting the 340B program and creating new opportunities for member hospitals to save on pharmaceuticals.

About the Position

Safety Net Hospitals for Pharmaceutical Access is hiring a pharmacist or other professional with experience in pharmacy operations to work full time for our Washington, D.C.-based non-profit hospital advocacy organization. Candidate must have experience in analyzing drug pricing data and with participating in the federal 340B drug discount program. Experience with pharmaceutical manufacturer patient assistance programs and the Medicare Part D program is preferred but not required. Experience at a disproportionate share hospital that participates in the 340B program is a significant plus. Public speaking experience and strong writing skills are also a plus.

Responsibilities

- Provide pharmacy expertise to staff, members and outside organizations
- Take lead role in conducting and supervising various pricing analysis projects for organization
- Recruit new member hospitals and corporate partners to SNHPA
- Recruit exhibitors/sponsors for conferences
- Assume lead role in coordinating conferences, workshops, teleconferences, webcasts, including developing agenda and recruiting speakers
- Liaison to other pharmacy organizations (ASHP, APhA, etc.), industry groups and the 340B Prime Vendor Program, Pharmacy Services Support Center and other 340B-related organizations
- Serve as lead contact with members and industry on patient assistance programs
- Provide support to SNHPA’s regulatory and legislative team on pharmacy-related matters
- Draft letters, news articles, conference descriptions, policy pieces and other documents as needed
- Assume other duties that require pharmacy expertise

Pay is based on experience. More information about SNHPA can be found at www.safetynetrx.org. Please send cover letter and resume to admin@safetynetrx.org or fax to at 202-552-5868. Please state the starting date of your availability, your salary requirements and how you became aware of this job opening.

Clinical Pharmacy Initiative continued from pg. 4

and test an online business tool.

To further expand on the goals of the initiative, HRSA recently sent a team to the Patient Safety Improvement Corps, which is a partnership program between the Agency for Healthcare Research and Quality and the Department of Veterans Affairs. The program aims to improve patient safety by providing knowledge and skills to teams of health care providers from various fields. The program consists of three, week-long sessions—one week in September, January and May. OPA proposed two teams, but only one was selected.

“It’s a tremendous opportunity, and we are thankful we could take advantage of it,” Mitchell says.

The four team members are: Tanya Grandison, a public health analyst with HRSA’s Center for Quality, Lisa Kivela, the administrative director of pharmacy for the Harris County Hospital District in Houston, Texas, Dan Rehrauer, the pharmacy director at Westside Community Health Services in St. Paul, Minn., and Krista Scardina, an OPA pharmacist and program management officer.

Tamper-Resistant Pad Requirement continued from pg. 5

included an amendment that would have imposed a two-year moratorium that was to be paid for by increasing the manufacturer rebates payable under the Medicaid rebate program. The rebate increase was removed from the bill.

Twelve states already require the use of tamper-resistant pads in certain cases, and New York requires it for all prescriptions. CMS will require that state laws and regulations meet or exceed the requirements set forth in the May provision.

Pilot Project continued from pg. 8

In addition to the pilot project, OPA has been receiving quarterly 340B pricing files from a number of manufacturers on a voluntary basis to better monitor the accuracy of manufacturer pricing (See Feb. 2006 Monitor).

According to Mitchell, twelve manufacturers originally expressed interest in the project: Genentech, GlaxoSmithKline, Schering-Plough, Daiichi Sankyo, Amylin, Amgen, Lilly, Johnson & Johnson, Watson, Wyeth, Novo Nordisk and AstraZeneca. Of the 12, six are currently participating in the program. One wholesaler, Morris and Dickson, is also participating in the project, and others are expected to join.
Innohep® is a low-molecular weight heparin indicated for the treatment of acute symptomatic deep vein thrombosis (DVT) with or without pulmonary embolism when administered in conjunction with the oral anticoagulant warfarin sodium. The safety and effectiveness of Innohep® were established in hospitalized patients.

For additional information, please visit www.innohepusa.com.

Spinal or epidural hematomas can occur with the associated use of low molecular weight heparins and spinal/epidural anesthesia or spinal puncture, which can result in long-term or permanent paralysis. The risk of hematomas is increased by the use of postoperative indwelling epidural catheters or by the concomitant use of drugs affecting hemostasis such as NSAIDs, platelet inhibitors, or other anticoagulants. Patients should be frequently monitored for signs and symptoms of neurological impairment. If neurological impairment is noted, urgent treatment is necessary (see Full Prescribing Information).

Patients with active major bleeding, patients with (or a history of) heparin-induced thrombocytopenia, or patients with known sensitivity to heparin, tinzaparin sodium injection (or any of its constituents), or pork products should not be treated with Innohep®. Innohep® should be used with extreme caution in conditions with increased risk of hemorrhage.

Bleeding is the most common adverse event associated with Innohep®, and can occur in any tissue or organ. The most common adverse events in controlled clinical trials with Innohep® were injection site hematomas (16%), abnormal elevations of AST (8.8%) and ALT (13%), urinary tract infections (3.7%), pulmonary embolism (2.3%), and chest pain (2.3%). Other bleeding events associated with Innohep® at a frequency of ≥1% were epistaxis (1.9%), hemorrhage (1.5%), hematuria (1%), and thrombocytopenia (1%).

Innohep® cannot be used interchangeably (unit for unit) with heparin or other LMWHs as they differ in manufacturing process, molecular weight distribution, anti-Xa and anti-IIa activities, units, and dosage. Each of these medications has its own instructions for use.
Subscribe online at www.drugdiscountmonitor.com

or

Mail or fax subscription form to:

The Federal Drug Discount and Compliance Monitor
1501 M Street, NW, 7th Floor
Washington, DC 20005
Fax: (202) 552-5868

For questions concerning The Monitor, contact Katie O’Dowd at katie.odowd@drugdiscountmonitor.com or (202) 552-5853.

Contact Name: ________________________________
Title: ________________________________
Organization: ________________________________
Mailing Address: ________________________________________________
Billing Address: ________________________________________________
Email: __________________ Phone: __________________

<table>
<thead>
<tr>
<th>Subscriptions</th>
<th># of users</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Online access: Nonprofit</td>
<td>1</td>
<td>$200</td>
</tr>
<tr>
<td>and government</td>
<td>up to 5</td>
<td>$500</td>
</tr>
<tr>
<td></td>
<td>up to 10</td>
<td>$800</td>
</tr>
<tr>
<td></td>
<td>Unlimited</td>
<td>$1200</td>
</tr>
<tr>
<td>Online access: For profit</td>
<td>1</td>
<td>$400</td>
</tr>
<tr>
<td></td>
<td>up to 5</td>
<td>$800</td>
</tr>
<tr>
<td></td>
<td>up to 10</td>
<td>$1200</td>
</tr>
<tr>
<td></td>
<td>Unlimited</td>
<td>$2000</td>
</tr>
<tr>
<td>Print Copies</td>
<td>max. one per online user</td>
<td>$100 each</td>
</tr>
</tbody>
</table>

Method of Payment

☐ Check (payable to “The Monitor”)

☐ Bill Me

☐ Credit Card
Type: ________________________________
Name on Card: __________________
Card #: __________________
Expiration: __________________
CVV Code: __________________

TOTAL COST = __________

I have read and agreed to the site license located at www.drugdiscountmonitor.com.

Signature: ________________________________________________