

## OPA Approves Innovative Demonstration Project in Texas

A coalition of safety net providers in Texas has begun developing an innovative new Alternative Methods Demonstration Project that may allow all of the coalition's 340B entities to expand access to pharmaceuticals for its 340B-eligible patients.

Under the program, the four 340B entities in Travis County—a disproportionate share hospital (DSH), a 14-site community health center network, a family planning clinic, and a primary care clinic for the uninsured—have already been authorized to contract with a retail pharmacy chain to make their 340B drugs more easily accessible.

The program, formally approved by the Office of Pharmacy Affairs (OPA) late last year, is being organized by the Indigent Care Collaboration (ICC), an alliance of health care providers spanning a six county area that develops health care programs to serve low income patients in central Texas.

ICC collects and maintains electronic medical records on all of the patients seen at participating clinics in a shared system. ICC also coordinates pharmacy programs aimed at providing access to low cost and free drugs, a mission that attracted ICC to the Alternative Methods Demonstration Project program.

Jodie Baldwin, Director of Pharmacy Programs at ICC, says the organization has been interested in developing a demonstration project for its 340B entities for a number of years that would improve patient access.

"ICC has submitted several different versions of this program to OPA over the last three or four years," she says,

adding that ICC initially encountered a number of regulatory roadblocks.

One obstacle with the program was that ICC includes both 340B and non-340B entities, which raised concerns at OPA and the U.S. Department of Health and Human Services Office of Inspector General (OIG), according to Baldwin.

"They wanted to ensure that non-340B entities did not receive the benefit of the program," she says.

In response to these concerns, ICC agreed to have each participating entity apply for the demonstration project separately. Meanwhile, ICC maintains the responsibility of implementing the program and negotiating contracts with its contracted pharmacy chain.

So far, the four covered entities in Travis County are the only providers enrolled, although Baldwin says that ICC will encourage others to join when the program begins showing tangible savings.

"This is our pilot project," says Baldwin. "We want to make sure it is successful and then offer it to other ICC entities."

That being said, the program is still in its development stage because ICC's initial pharmacy partner, a local supermarket, has chosen not to participate.

However, Baldwin says that ICC is in negotiations with a large pharmacy chain that already has a strong relationship with the city of Austin. The Alternative Methods Demonstration Project program was introduced by the US Department of

Health and Human Services (HHS) in 2001 as a way for 340B entities to increase access to pharmaceuticals and lower costs.

The program allows 340B providers to (1) create a network of 340B entities that use a common pharmacy to dispense drugs, (2) use multiple contract pharmacies, or (3) enter into a contract pharmacy arrangement to supplement an in-house pharmacy.

The programs are subject to approval and review by OPA and are granted specific time limits during which to operate. There are currently 15 demonstration projects in operation, according to the OPA website. These programs generally expire after a period of 6-7 years, although the terms vary by program.

Most of these programs were designed to allow individual entities to use multiple contract pharmacies, although a handful have been used to create pharmacy networks.

One tangible result of this program is that, based on the experiences of entities that operate demonstration projects, OPA plans to issue guidelines in the near future that would lift the restriction against covered entities contracting with more than one pharmacy to dispense its 340B drugs.

OPA Director Jim Mitchell told *The Monitor* in August 2005 that existing demonstration projects have provided the agency with evidence that multiple contract pharmacy arrangements can easily be developed with sufficient controls against potential diversion. A *Federal Register* notice explaining this policy is expected in the near future.