Specialty Pharmacy Continuum

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AMCP Launches Biosimilar Programs for Data Collection, Better Policy Compliance

by Marie Rosenthal

ORLANDO, FLA.—At the AMCP Nexus 2015 meeting, the Academy of Managed Care Pharmacy announced the formation of two new programs: One will collect and provide information about biologics and biosimilars and the other will offer a resource concerning state and federal regulations that affect managed care pharmacy. The programs will launch in early 2016.

The Biologics & Biosimilars Collective Intelligence Consortium (BBCIC) will be an active monitoring system that will draw on large sets of de-identified pharmacy and medical data from 100 million lives to provide unbiased scientific information about the safety and efficacy of marketed biosimilars and their corresponding novel biologics.

The consortium is the only research network dedicated to active monitoring of these biological products. The framework will apply the same scientific, analytic methods used by the FDA Sentinel initiative, a postmarketing surveillance system that tracks the safety of therapies once they reach the market.

“The BBCIC initiative reflects our continuing commitment to public safety and health by evaluating possible issues concerning biologics and biosimilars,” said AMCP CEO Edith A. Rosato, RPh, IOM. The initiative will “provide patients and insurers the reassurance they need to use these new therapies,” she said at a press conference held during the AMCP Nexus meeting.

The new group will involve a collaboration of managed care organizations, integrated delivery systems, pharmacy benefit management firms, research institutions and pharmaceutical companies. The effort comes as the first biosimilar, Zarxio (filgrastim-sndz), from Sandoz, enters the U.S. market.

As more biosimilars come to market, physicians, patients and other stakeholders will have questions about the safety and effectiveness of these products, said Bernadette Eichelberger, PharmD, the program director of the BBCIC. Although Europeans have had a decade of experience with biosimilars, they only have small registries collecting this type of data. Dr. Eichelberger expected the BBCIC to enable U.S. providers to become aware of any safety and efficacy issues much faster due to the number of lives that are being surveyed, as well as the robustness of the data collected. One of the key features of the consortium is that all of the collected data parameters, such as laboratory results, will be standardized, and researchers will be comparing apples with apples.

The consortium will regularly analyze and publish results of the surveillance, she said, adding that transparency is paramount to the success of the program.

“AMCP believes that the public’s and health care community’s understanding of biosimilars will be enhanced by the BBCIC’s balanced scientific approach,” Ms. Rosato explained. “If biosimilars are actively monitored after their introduction for safety and effectiveness, this will answer questions and concerns, leading to their greater acceptance and adoption in the U.S.”

Biosimilars are highly similar, independently developed versions of original (reference) biological medicines. It is expected that biosimilars will expand access to patients because they will be considerably less expensive than the reference product.

To date, the following organizations have made financial and in-kind commitments to the BBCIC initiative: AbbVie, Amgen, Anthem, Boehringer Ingelheim, Group Health Research Institute, Harvard Pilgrim Health Care, HealthPartners, Henry Ford Health System and Merck. Other BBCIC founding partners are finalizing contracts. For more information about the program, visit www.BBCIC.org.

Subscription-Based Resource

The second program is a beta rollout of the State and Federal Pharmacy Intelligence Resource (SAFPhIR), AMCP's new subscription-based offering that combines intelligence on recently enacted laws and regulations affecting managed care pharmacy with expert policy analysis and high-level guidance.

The new resource contains many features that set it apart from other legislative and regulatory databases. These include the ability to tailor the information a user receives based on his or her state and federal priorities, and the ability to access a wealth of expert policy analysis and guidance that will make the content actionable for the entire managed care operation.

"Government affairs will certainly appreciate SAFPhIR's highly tailored, highly valuable content, but other parts of the business and industry operations also will benefit from understanding the practical implications of policy and regulatory changes," Ms. Rosato said. "There is a need in the health care marketplace for timely information on the multitude of federal and state mandates affecting managed care pharmacy and industry each year. AMCP is pleased to fill that need with SAFPhIR."

As many as 500 bills affecting managed care pharmacy are introduced every year in state legislatures, about 150 of which are signed into law. The product's Web- and tablet-friendly application features the capability of designing content feeds based on each user's unique needs. For instance, some users may only be interested in new state and federal laws and regulations affecting opioid utilization, whereas others may be interested in laws affecting biosimilars.

"SAFPhIR will provide users information they need to make informed decisions about their business," said Tom Donnelly, AMCP's vice president of SAFPhIR. "If there is a new law in California that will impact pharmacy benefit management companies, for example, we will have that coupled with expert analysis to provide guidance on how to meet the letter of the law."

Mr. Donnelly is seeking beta test customers who will get exclusive early access to the tool and provide input on making improvements. Beta users also will receive valuable discounts on ongoing subscriptions.

For more information, visit the website at www.safphir.com.