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Academy of Managed Care Pharmacy

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By Susan Cantrell

To say that our health care system is undergoing enormous change is not a cliché, it's an understatement. The incoming Trump administration and GOP-controlled Congress have vowed to repeal and replace the Affordable Care Act immediately, a move that could bring tectonic changes to an already turbulent system.

Whatever the impact is to managed care pharmacy, AMCP and its more than 8,000 members will continue to fulfil its mission to the more than 270 million Americans covered by a pharmacy benefit. And that is to serve society by using sound medication management principles and strategies to improve health care for all.

Meanwhile, we expect to address many other pharmacy-related changes in the coming year. Here are some of them:

FDAMA Section 114

A key issue that could be considered early in 2017 is the proposed expansion of off-label communications between biopharmaceutical companies and health plans and other entities that make formulary and coverage decisions. Currently, the Food and Drug Administration restricts the sharing of product information not included in the drug label, which greatly hinders the sharing of health care economic information (HCEI). With the U.S. health care system's increased focus on value, we believe it is essential that pharmaceutical HCEI is disseminated to decision makers, such as pharmacy and therapeutic (P&T) committees, and integrated delivery systems, in a manner that comports to good research standards.

In response, AMCP has teamed up with a diverse group of stakeholders — from health plans and other payers to biopharmaceutical manufacturers and patient organizations — to encourage appropriate expanded off-label product communications.

On the regulatory front, this alliance is calling on the FDA to issue the long-awaited guidance clarifying Section 114 of the Food and Drug Administration Modernization Act (FDAMA) of 1997, which created a regulatory safe harbor for companies to share HCEI with decision makers. Without implementing guidance, Section 114 has been little used because of ambiguity in its wording. Fortunately, FDA has indicated that guidance is forthcoming. To help inform the agency, AMCP held a forum in the spring that resulted in these consensus recommendations:

- Expand HCEI to include health care utilization (e.g., hospitalizations, emergency department visits), patient benefits, adherence, endpoint extrapolations, quality of life and adverse events.
- Define "competent and reliable scientific evidence" — which will form the basis of HCEI — as "truthful and non-misleading tests, analyses, research, studies, models or other evidence."
- Expand the list of entities eligible to receive HCEI beyond P&T and formulary committees to integrated delivery systems, other entities that make health care decisions for patient populations, and organizations that evaluate HCEI or develop value frameworks and compendia.

The recommendations also noted that the current AMCP Format for Formulary Submissions and the eDossier system is one format well suited to seek HCEI from manufacturers, among other options.

On the legislative front, AMCP and the other stakeholder organizations also will urge Congress to clarify and responsibly expand FDAMA Sec. 114's safe harbor as part of the must-pass Prescription Drug User Fee Reauthorization (PDUFA) legislation.

Preapproval Information Exchange (PIE)

During discussions regarding FDAMA Section 114 another communication issue emerged: the desire among payers to exchange information with biopharmaceutical companies on products that are within 12 to 18 months of FDA approval. Currently federal laws and regulations significantly restrict preapproval communications.

Early dissemination — with safeguards in place to limit unintended dissemination — would allow decision makers to build this information into their financial forecasting for the plan year ahead. By knowing about groundbreaking new therapies and their potential to affect large numbers of patients, health plans and other risk-bearing decision makers can design benefits that keep premiums and other costs in check as much as possible. The recent introduction of high-cost medications has added urgency to the need for better and earlier evaluation and preparation.

Early dissemination also benefits patients: it would allow decision makers to better evaluate the increasing number of medications approved on an expedited basis, where often detailed clinical information is not available. Having this information early would allow plans to start paying for them on day one.

A second AMCP forum on the topic developed recommendations on what the participating stakeholders call Preapproval Information Exchange. Named "PIE," this proposed process would allow communications between manufacturers and payers and other population health decision makers, and reflects the fact that some of the information used for premium determination or insurance-rate setting will not always include typical clinical or economic data. In 2017, AMCP will continue to urge Congress to approve legislation establishing PIE.

SNOMED: Documenting MTM services

Another important focus in 2017 is adoption of standardized terms for medication therapy management (MTM) services in electronic health record systems. AMCP has helped lead efforts with other pharmacy organizations, community and chain pharmacies, health plans, PBMs, and MTM vendors to develop a framework for documenting MTM services using SNOMED CT (Systematized Nomenclature of Medicine: Clinical Terms) codes.

MTM quality measures will be a key focus.

These codes provide the standard clinical terminology needed for providers to exchange clinical information electronically and report consistent quality measures. The framework links SNOMED CT codes to the MTM services that pharmacists perform to document and communicate this information with other health care providers and payers through electronic health records and other standardized systems. This will allow providers, public and private payers and other health care stakeholders to evaluate and compare MTM services across various provider types, health care settings and patient populations to determine those services that provide the best outcomes.

AMCP and other representatives from the pharmacy profession will stay engaged on this issue as the framework is implemented in 2017. We also will review and update the framework as evidence from the Medicare Part D Enhanced MTM Model becomes available.

Opioid abuse and misuse

In 2017 our work to address addiction and opioid abuse and misuse will continue. We will:

- Advocate appropriate implementation of two provisions in the 2016 Comprehensive Addiction and Recovery Act (CARA). The first is a provision that gives Medicare Part D plans (PDPs) the authority to establish drug management programs for at-risk beneficiaries — programs that have successfully limited unnecessary prescriptions in commercial plans and Medicaid. They allow PDPs to identify at-risk beneficiaries and have them obtain opioid prescriptions through a single pharmacy and prescriber.

The second is a provision to reauthorize the National All Schedules Prescription Electronic Reporting Act (NASPER), which provides states with grants to improve their prescription drug monitoring programs (PDMPs). Such programs prevent the misuse, abuse and diversion of controlled substances by permitting qualified prescribers and pharmacists to access patient-specific information before issuing or dispensing a prescription. AMCP is also supports allowing more access to PDMPs by payers.

- Share recommendations from the recent AMCP Foundation annual research symposium, "Balancing Access and Use of Opioid Therapy." Experts discussed how health plans, providers, advocacy groups, payers and other stakeholders can best work together to ensure that patients have appropriate access to opioid pain therapies, while preventing their abuse. The recommendations can be found at www.amcp.org/FdnSymp_2016Report/.
- Share findings from the AMCP Addiction Treatment Advisory Group (ATAG). Developed for managed care organizations, the findings include increasing access to naloxone and other medication-assisted treatments, evaluating benefit designs to decrease potential barriers and providing education and support to increase awareness about naloxone. Because of the central role managed care plays in population management, among other reasons, managed care organizations are uniquely positioned to provide solutions to the complicated problems of addiction treatment. The ATAG findings are at http://bit.ly/2fJogY9.

Next steps with biosimilars

AMCP has a major stake in ensuring that biosimilars are widely accepted and utilized. In 2017 AMCP will focus on ensuring a robust pathway is in place for these products, and build on education and outreach to health care providers about biosimilars. These efforts include:

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- FDA Biosimilar Guidance: AMCP continues to call on the FDA to draft, revise, and/or finalize several guidance documents around biosimilars, including naming, labeling and interchangeability. Not only should these guidance documents be published as quickly as possible, but the FDA must also ensure they are harmonious with one another to truly operationalize the biosimilars pathway.
- Biosimilars Resource Center (BRC): AMCP will continue to expand the BRC, an unbiased, policy-neutral repository of educational resources and information on biosimilars for pharmacists, physicians, nurses and other health care providers. The site was developed in partnership with leading national pharmacy organizations and can be accessed at www.biosimilars-resourcecenter.org.
- The Biologics & Biosimilars Collective Intelligence Consortium. Formed in 2015, BBCIC is a science-based, nonprofit, public service initiative that will monitor biosimilars and corresponding novel biologics for effectiveness and safety. BBCIC research will use large sets of de-identified medical and pharmacy data covering 100 million people. BBCIC recently posted research protocols that will lay the groundwork for studies of biosimilars currently available or projected to enter the market next year. The protocols — posted on www.clinicaltrials.gov — will look at biologic anti-inflammatory therapies, colony stimulating factors and long-acting insulins.

A precursor to actual observational research studies, these protocols establish indicators to be measured by characterizing patient populations, identifying exposures and outcomes, as well as patterns of use and clinical risk factors that may influence patient response.