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FDA Releases Draft Guidance on FDAMA Section 114 and Preapproval Information Exchange (PIE)

Guidance Largely Aligns With Academy's Consensus Recommendations

The FDA released long-awaited draft guidance on Jan. 18 titled "Drug and Device Manufacturers Communications With Payors, Formulary Committees, and Similar Entities – Questions and Answer." The guidance document describes the FDA's current thinking on:

- Communication of health care economic information (HCEI) to payors regarding approved drugs under Section 114 of the Food and Drug Administration Modernization Act of 1997 (FDAMA Section 114) and Section 3037 of the 21st Century Cures Act; and
- Communications to payors about investigational products that have yet to be approved by the FDA for any use.

AMCP has been actively engaged in developing multi-stakeholder consensus recommendations to the FDA for guidance development regarding these topics during two recent partnership forums on FDAMA Section 114 and Preapproval Information Exchange (PIE). AMCP has also led adoption and advocacy efforts with the FDA and Congress to have these recommendations implemented to best meet the needs of its members to support drug selection, formulary management, and coverage and reimbursement decisions for the populations they serve.

AMCP applauds the FDA for expeditiously addressing these very important topics and for its careful consideration of the consensus recommendations developed during the AMCP partnership forums. (Read AMCP statement)

Overall, the FDA draft guidance is largely consistent with the consensus recommendations developed during the two AMCP partnership forums with some minor differences. AMCP will provide comments to the docket in advance of March 20, 2017 and highlight the areas of minor difference, encouraging the FDA to reconsider these areas to align with the consensus recommendations developed during the two AMCP partnership forums.

AMCP is developing a summary of the guidance that will be available soon.

AMCP Releases Recommendations Proposing Creation of a Safe Harbor for Preapproval Information Exchange

The Academy published a set of consensus recommendations in the January 2017 issue of the Journal of Managed Care & Specialty Pharmacy (JMCP) to allow biopharmaceutical companies to proactively share clinical and economic information with population health decision makers on emerging therapies in advance of FDA approval, an area that is significantly restricted by current federal laws and FDA regulations. Over the past several years, population health decision makers have expressed a need for proactively receiving this information in advance of FDA approval, as long as appropriate safeguards are put into place to prevent this information from reaching unintended entities.
Read more. Read the recommendations here.

FEDERAL LEGISLATIVE UPDATE

115th Congress Convenes, Starts Work on ACA Replace and Repeal

The 115th Congress convened at noon on Jan. 3 and will remain in session through Jan. 3, 2019. The Senate, with a 51-48 GOP majority, and the House, with a 227-198 GOP majority, have taken the first steps to repeal the Affordable Care Act. The votes were to approve a budget resolution to allow “broad swaths of the Affordable Care Act to be repealed through the budget reconciliation process.” AMCP will continue to follow the “repeal and replace” efforts and advocate that patients served by managed care pharmacy not lose access to care, and that any “replacement” program will provide a high quality and affordable benefit. AMCP will closely follow any proposals to require government negotiation of drug prices, increase importation of drugs, and change the Medicare and Medicaid programs.

21st Century Cures Law Enacted

The 21st Century Cures Act (H.R. 34) passed the House on Nov. 30, 2016, by a 392-26 vote, and the Senate on Dec. 7, 2016, by 94-5 vote. President Obama signed it into law on Dec. 13, 2016 (Pub.L No.114-255). The Act contains three primary titles that address acceleration of medical product discovery, development, and delivery. The Act contains $4.8 billion in spending over 10 years for new research at the National Institutes of Health, including $1.8 billion for the cancer research “moonshot” championed by Vice President Biden, and $1.4 billion for the Precision Medicine Initiative, a project supported by President Obama to collect genetic data on one million American volunteers that will be used to help develop new treatments. The nation's prescription drug abuse crisis also is addressed in the legislation. States will receive grants worth $1 billion over the next two years for drug abuse prevention and treatment programs. A number of

Advocacy Tip

Congress, as well as nearly all the State Legislatures, have convened for 2017. Now is a great time to check in on your legislators on both the state and federal level to see what their priorities are for 2017. You can find this information by visiting you legislators’ Facebook, Twitter, and official website. Phone calls and emails are also a good way for you to share your thoughts with your legislators (check their official websites for contact information). Your advocacy efforts are an important factor in helping to shape public policy.

provisions in the Act also are aimed at swift approval of new drugs and devices. Many have applauded these new measures, but critics say those provisions could raise the risk of harmful treatments getting to the marketplace. Read more here. A link to provisions of the law that are relevant to AMCP members can be found here.

Alliance for a Stronger FDA Will Continue Push for Adequate FDA Funding

In her cabinet exit memo, outgoing HHS Sec. Sylvia Burwell urged the Trump Administration to increase FDA funding. In her rationale, she pointed to the need to improve regulatory science and stated that "a robust FDA will help improve competition in the marketplace, especially the pharmaceutical marketplace where health care consumers want access to safe and affordable options." We are awaiting a decision on the confirmation of Tom Price, as HHS Secretary as well as a decision on the next leader of the FDA. However, the Alliance for a Stronger FDA believes that every year will be a battle to obtain the funding levels FDA needs, and that as supporters of the FDA, the Alliance must be even more effective advocates for the FDA's budget in 2017 and beyond.

FEDERAL REGULATORY UPDATES

FDA Releases Draft Guidance for Determining Biosimilar Interchangeability

The FDA released draft guidance on Jan. 17 titled "Considerations in Demonstrating Interchangeability With a Reference Product." The highly anticipated draft guidance document outlines the FDA's current thinking on demonstrating interchangeability of biosimilars with a reference biologic product under section 351(k)of the Biologics Price Competition and Innovation Act of 2009 (BPCIA). In general, the FDA outlines a flexible step-wise approach to demonstrating interchangeability and purposely avoids being too prescriptive recognizing that a one-size-fits-all approach is not feasible given the complexity of biological and biosimilar products. Sponsors will be required to submit data from switching studies to meet the requirements under Section 351(k)(4)(B) of the BPCIA and demonstrate that the risk in terms of safety or diminished efficacy of alternating or switching between use of the proposed interchangeable and the reference product is no greater than the risk of using only the reference product. The FDA also iterates numerous times throughout the draft guidance that it encourages sponsors to engage in early discussion with the FDA regarding their product development plans. Read more here.

FDA Finalizes Biosimilars Naming Guidance

The FDA released a final guidance on Jan. 12 titled "Nonproprietary Naming of Biological Products." The final guidance closely mirrors the draft guidance document that was released in August 2015, on which AMCP has submitted detailed comments. Under the final guidance: Prospectively, all biosimilar products will be designated a nonproprietary name that includes a unique suffix composed of four lowercase letters; Retrospectively, all biological innovator products currently on the market will have their nonproprietary name amended to include a unique suffix composed of four lowercase letters. Read more here.

SAMHSA Releases Final Rule to Modernize Confidentiality Requirements for Patients Seeking Treatment for Substance Use Disorders

The Substance Abuse and Mental Health Services Administration (SAMHSA) issued a Final Rule on Jan. 13 to update and modernize the Confidentiality of Alcohol and Drug Abuse Patient Records regulations (Part 2 Regulations). The provisions in the Final Rule are effective Feb. 17. Under the existing Part 2 Regulations, a federally assisted substance use disorder program generally may only release identifiable information related to substance use disorder diagnosis, treatment, or referral for treatment with an individual's express consent. Even disclosures related to payment, treatment, or health care operations, which are permissible under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) without patient authorization, require express consent. Read more here.

AMCP Submits Comments to CMS on the Medicare Part D MTM Program Standardized Format

AMCP submitted comments Dec. 30, 2016, to CMS on the notice titled "CMS-10396 Medication Therapy Management Program Improvements" published in the Federal Register on Oct. 31, 2016. Under the notice, the Medicare Part D Medication Therapy Management (MTM) Program Standardized Format ("standardized format") would be reauthorized in its current format for an additional three years through 2020. AMCP strongly urged CMS to work with the pharmacy profession to modernize, test, and validate alternate formats to maximize its intended benefit for Medicare beneficiaries and to work towards implementing a new standardized format in advance of 2020. AMCP presented CMS with initial suggestions developed by the AMCP MTM Advisory Group on how the standardized format may be improved to align with updates in technology and the need for beneficiaries to have choice in how they receive this information. These recommendations are intended to serve as an opportunity to begin dialogue with CMS in this area to see how the pharmacy profession and CMS can work together to improve the standardized format to maximize the beneficiary experience. The full comment letter is available here.

UPCOMING REGULATORY COMMENT PERIODS

AMCP is seeking stakeholder feedback on the following proposed rules that are currently open for comment. Please provide feedback via email to Soumi Saha, Assistant Director of Pharmacy & Regulatory Affairs, at ssaha@amcp.org by the dates listed for incorporation into AMCP's comments on the matter. All of AMCP's final comment letters are available on the AMCP website and also included in the Legislative-Regulatory Briefing Newsletter that is sent to all AMCP members.

Topic	Feedback to AMCP	Comments Due
Biosimilars Interchangeability	March 10	March 19
Medical Product Communications Consistent With FDA-Required Labeling: Questions and Answers	March 10	March 19
Drug and Device Manufacturer Communications With Payors, Formulary Committees, Similar Entities: Questions and Answers	March 10	March 20
Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products	March 17	April 10

Upcoming Webinars

Introduction to the Impact of Resistance in Hepatitis C
A Science & Innovation Theater Webinar sponsored, developed and presented by Abbvie
Wednesday, February 1, 2017, 2-3pm, ET

Highlighting Trends in Pain Management
A Science & Innovation Theater Webinar sponsored and developed by Daiichi Sankyo, Inc.
Thursday, February 9, 2017, 2-3pm, ET

For more information or to register, please visit:
www.amcp.org/calendar/

STATE LEGISLATIVE UPDATE

Eye on State Legislatures

This month began with 43 state legislatures in session and seven others pre-filing bills for 2017 as they prepare to begin their sessions later in the year. AMCP anticipates drug price transparency, biosimilar substitution, PBM regulation, mandated coverage for medication synchronization and required coverage of abuse deterrent formulations of opioids to be major issues in 2017. AMCP will closely monitor these issues and any other issues that impact managed care pharmacy.

Biosimilars:
In 2016, Ohio Governor John Kasich signed OH HB 505 into law on December 19th. Massachusetts and Michigan were the only other states with pending legislation in December; however, both of those bills (MA HB 976) and (MI HB 4812) died when their respective state legislatures ended for 2016. In 2016, eight states in addition to Ohio, enacted biosimilar legislation (AZ, HI, ID, KY, MO, OR, RI, and PA).

In 2017, South Carolina (H 3438), Montana (HB 233), and Nebraska (LB 481) have introduced biosimilar legislation. These bills have language substantially similar to the bills we saw in 2016. Generally, they would permit interchangeable biological substitution by a pharmacist when not expressly prohibited by a prescribing physician. They would also require a pharmacist to provide certain prescriber notification and post-dispensing record keeping. AMCP will send letters opposing these additional administrative record keeping and post-dispensing communication requirements which are not required for any other FDA approved drug category.

States where AMCP expects to see biosimilar legislation introduced in 2017 include: AK, AL, AR, CT, IA, KS, MN, NM, NV, NY, and VT.

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