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FDA Releases Final Guidance Documents on Biosimilars

Following the approval of its first biosimilar product earlier this year, the U.S. Food and Drug Administration (FDA) issued three final biosimilar guidances in order to provide predictability and further clarity on scientific and regulatory considerations for sponsors initiating biosimilar development programs. **Read below**

HHS Announces $384 Million in Savings from Pioneer Accountable Care Organization Model

The independent evaluation report released by the Department of Health and Human Services on May 4 finds that the Pioneer Accountable Care Organization Model generated over $384 million in savings to Medicare over its first two years. **Read below**

PACT Coalition Endorses Cancer Care Payment Reform Act of 2015

The Patient Access to Community Treatment (PACT) coalition recently commended Congresswoman Cathy McMorris Rodgers for introducing the Cancer Care Payment Reform Act of 2015 (H.R. 1934) and fully endorsed the legislation in an April 21 letter. **Read below**

HRSA Launching 340B Ceiling Price Verification System

The Health Resources and Services Administration (HRSA) announced on April 24 plans to launch a system that verifies the accuracy of drug manufacturers' 340B ceiling prices. **Read below**

Congressional Lawmakers Release Updated Draft of 21st Century Cures Bill

House Energy and Commerce leaders unveiled an updated draft of the 21st Century Cures bill on April 29. The release of the 200-page document – which aims "to bridge the gap between advances in science and medicine" and determine how breakthrough therapies are regulated – comes on the heels of a yearlong negotiation process.

According to the official E&C Committee release, the discussion draft includes provisions to:

- Incorporate the patient perspective in the discovery, development, and delivery process;
- Increase funding for the National Institutes of Health, both through reauthorization and $10 billion over five years in mandatory funding, starting in FY 2016;
- Foster development of treatments for patients facing serious or life-threatening diseases;
- Modernize clinical trials;
- Break down barriers to increased collaboration and data sharing among patients, researchers, providers, and innovators;
- Help the development of personalized and precision medicines; and
- Provide clarity for developers of software products used in health management and medical care.

Placeholder language also was included for provisions intended to:

- Provide for continued work in the telehealth space;
- Repurpose drugs for serious or life-threatening diseases and conditions; and
- Establish the interoperability of electronic health records.

The updated draft, however, dropped a number of priority items included in the initial discussion document, which was released in January. Most notably, two provisions, one that would grant longer exclusivity periods for drug manufacturers of seldom-used therapies and another to give U.S. generic drug manufacturers longer protection periods from overseas competition, were removed.

For the section-by-section summary, CLICK HERE.

For the one-page bill summary, CLICK HERE.

Following Draft Release, Lawmakers Seek Feedback from NIH & FDA

One day after the updated 21st Century Cures discussion draft was released, the House E&C Subcommittee hosted a hearing, which featured officials from both the National Institutes of Health (NIH) and the U.S. Food and Drug Administration (FDA). Leaders

from both major stakeholders – as well as lawmakers – reacted to the draft legislation, and offered considerations for the future.

Specifically, witnesses at the hearing included:

- Dr. Kathy Hudson, *NIH Deputy Director for Science, Outreach, and Policy*
- Dr. Janet Woodcock, *FDA Director of the Center for Drug Evaluation and Research*
- Dr. Jeff Shuren, *FDA Director of the Center for Devices and Radiological Health*

Dr. Hudson expressed general excitement regarding increased biomedical funding. She also approved of bill language that directs NIH to develop a strategic plan – something research advocates had criticized in an earlier draft. Following the hearing, NIH Director Francis Collins said that the agency hopes to release a draft plan by August and issue the final plan by December.

FDA representatives were more skeptical of the new legislation, expressing concern that additional tasks – such as establishing new drug approval pathways – may hinder the agency's ability to effectively complete its primary goal: evaluating drug safety.

To watch the full hearing, CLICK HERE.

To read the Committee press release, CLICK HERE.

FDA Releases Final Guidance Documents on Biosimilars

The U.S. Food and Drug Administration (FDA) recently issued three final biosimilar guidances in order to "provide predictability and further clarity on scientific and regulatory considerations for sponsors initiating biosimilar development programs."

Biosimilars are generic versions of modern – and oftentimes, very expensive – biologic treatments. The FDA approved its first biosimilar product, a cancer medication called Zarxio, this March, prompting the agency to issue explanatory documents.

Specifically, the three guidance documents were:

- ***Scientific Considerations in Demonstrating Biolsimilarity to a Reference Product:*** The guidance outlines a specific approach that manufacturers should take when attempting to prove biosimilarity, encouraging sponsors to consult the FDA throughout the process.

- ***Quality Considerations in Demonstrating Biosimiliarity to a Reference Protein Product:*** The guidance provides recommendations to sponsors on the scientific and technical information for the chemistry, manufacturing, and controls (CMC) section of a marketing application for a proposed biosimilar.

- ***Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2019:*** The guidance provides answers to common questions regarding "biosimilarity or interchangeability," "provisions related to requirement to submit a BLA for a “Biological Product,” and "exclusivity."

The final guidances, however, left a number of critical questions regarding biosimilar regulation unanswered. Most notably, the FDA failed to address “naming” for biosimilars, but announced that it plans to release official guidance on the issue later this year. Questions also remain regarding the establishment of interchangeability and requirements for biosimilar labeling.

For more information on biosimilar guidance, CLICK HERE.

HHS Announces $384 Million in Savings from Pioneer Accountable Care Organization (ACO) Model

The independent evaluation report released by the Department of Health and Human Services (HHS) on May 4 finds that the Pioneer Accountable Care Organization (ACO) Model created in the Affordable Care Act (ACA) generated more than $384 million in savings to Medicare in its first two years – which equals about $300 per participating beneficiary per year.

The independent Office of the Actuary to the Centers for Medicare & Medicaid Services (CMS) also certified this week that the Pioneer ACO Model is the first to meet the stringent criteria for expansion to a larger population of Medicare beneficiaries beyond those participating in Pioneer ACO models.

According to HHS, the Pioneer ACO Model already services approximately 600,000 Medicare beneficiaries, who when compared to their counterparts accessing care via fee-for-service (FFS) or Medicare Advantage plans, on average:

- Report more timely care and better communication with their providers.
- Use inpatient hospital services less and have fewer tests and procedures.
- Have more follow-up visits from their providers after hospital discharge.

The goal of Pioneer ACOs is to shift healthcare delivery toward a system that rewards providers based on the quality, not quantity, of patient care. According to previous reports, Pioneer ACOs generated Medicare savings of $279.7 million in 2012 and $104.5 million in 2013.

The *Journal of the American Medical Association* published the Pioneer ACO results in a report entitled “Pioneer Accountable Care Organizations vs. Traditional Medicare Fee

for Service With Spending, Utilization, and Patient Experience," on the same day HHS released the findings. According to JAMA, the objective of the report was to determine whether fee-for-service (FFS) beneficiaries aligned with Pioneer ACOs had smaller increases in spending and utilization than other FFS beneficiaries while retaining similar levels of care satisfaction in the first two years of the Pioneer ACO Model.

To view the Pioneer ACO Evaluation Findings from Performance Years One and Two, CLICK HERE.

To view the Office of the Actuary memo, CLICK HERE.

To view the HHS press release, CLICK HERE.

PACT Coalition Endorses Cancer Care Payment Reform Act of 2015

The Patient Access to Community Treatment (PACT) Coalition recently commended Congresswoman Cathy McMorris Rodgers (R-WA) for introducing the Cancer Care Payment Reform Act of 2015 (H.R. 1934) and fully endorsed the legislation in an April 21 letter.

The bill – which is currently under consideration of the House Ways and Means Committee – aims to reform Medicare Payment for cancer care through the establishment of a national Oncology Medical Home Demonstration Project. The bill is cosponsored by Congressman Steve Israel (D-NY).

"We are particularly supportive of the legislation's focus on patient satisfaction," the group wrote. "We believe through the creation of the oncology medical home, patients will ultimately receive more coordinated, higher quality treatments resulting in lower overall cost to the health care system. We also believe the legislation can help advance and preserve patient access to community-medical care."

The US Oncology Network is a member of the PACT coalition, which is an alliance of patient advocacy organizations, provider groups and health care distributors committed to ensuring that patients have access to quality, affordable community-based cancer care. The Community Oncology Alliance (COA) also expressed support for the legislation.

For the full PACT Coalition letter, CLICK HERE.

For the full text of H.R. 1934, CLICK HERE.

For a section-by-section of the bill, CLICK HERE.

For more information on the PACT Coalition, CLICK HERE.

HRSA Launching 340B Ceiling Price Verification System

The Health Resources and Services Administration (HRSA) announced on April 24 plans to launch a system that verifies the accuracy of drug manufacturers' 340B ceiling prices. HRSA plans to collect drug makers' price-setting data as well as verify previously submitted calculated drug prices.

HRSA submitted an Information Collection Request to the Office of Management and Budget (OMB) on April 21 proposing to collect Average Manufacturer Price, unit rebate amount, package sizes, National Drug Code, period of sale and manufacturer-determined 340B ceiling prices.

"Accurate and timely pricing data submissions are critical to successful implementation of the 340B Program, ensuring that covered entities have confidence that the amounts being charged are in accordance with statutorily-defined ceiling prices," the Federal Register notice states.

Under the Affordable Care Act (ACA), HRSA is to make ceiling prices of 340B drugs for hospitals and others who receive 340B drug discounts available to the public. The ACA also requires that HRSA protect "privileged pricing data from unauthorized re-disclosure."

Stakeholder groups, including the Pharmaceutical Research and Manufacturers of America (PhRMA), have warned that OMB's data collection is premature and goes beyond the statutory data collection requirements under the ACA.

Comments on the Information Collection Request are due to OMB by May 21, 2015.