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The White House has released additional details regarding the Administration's new Precision Medicine research program, which it hopes will revolutionize how the U.S. improves health and treats diseases. **Read below**

21st Century Cures Initiative Enters Legislative Phase

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HHS Unveils Plan to Revamp Medicare Payments

The Department of Heath and Human Services outlined a broad plan this month to incentivize quality over quantity in Medicare payments by overhauling traditional fee-for-service payment models with value-based purchasing programs. **Read below**

HHS Asks DC Court To Drop 340B Orphan Drug Lawsuit

The U.S. Department of Health and Human Services reportedly asked a D.C. federal court on January 27 to drop the Pharmaceutical Research and Manufacturers of America's complaint challenging a department rule on orphan drugs in the 340B program. **Read below**

President Obama Endorses Site-Neutral Payment Policies in FY2016 Budget Proposal

President Barack Obama released his $4 trillion FY2016 Budget on February 2, which contains more than $400 billion in proposed Medicare savings over 10 years. In addition to calling for a repeal of the Sustainable Growth Rate (SGR) formula, the President's budget also includes a proposal to institute site neutral payment policies across care settings, thereby leveling the playing field between the community and hospital setting and lowering costs to Medicare, taxpayers and beneficiaries.

Unfortunately, the President's budget also proposes certain provisions that would negatively impact community oncology, such as drastic reductions in drug reimbursement rates and the elimination of in-office ancillary service (IOAS) referrals for certain services.

Provisions proposed in the President's Budget of greatest interest to The US Oncology Network include:

Encourage Efficient Care by Improving Incentives to Provide Care in the Most Appropriate Ambulatory Setting

The Budget proposes to improve incentives for providing ambulatory care in the most appropriate clinical setting. This proposal would lower payment for services provided in off-campus hospital outpatient departments under the Outpatient Prospective Payment System to either the Medicare Physician Fee Schedule-based rate or the rate for surgical procedures covered under the Ambulatory Surgical Center payment system. These changes would be phased in over four years beginning in CY 2017, and Secretarial authority would be provided to adjust payments in the event beneficiary access problems arise.
Estimated Savings: $29.5 billion over 10 years

Exclude Certain Services from Medicare's In-Office Ancillary Services Exception

The Budget calls for the exclusion of radiation therapy, advanced imaging, pathology and therapy services from the in-office ancillary services exception (IOASE) unless a practice is clinically integrated and demonstrates cost containment.
Estimated Savings: $6 billion over 10 years

Modify Reimbursement of Part B Drugs

The Budget lowers payment from 106 percent of the average sales price to 103 percent of average sales price for Part B drugs administered in the physician office and hospital outpatient settings starting in 2016. If a physician's cost for purchasing the drug exceeds average sales price + 3 percent, the drug manufacturer would be required to provide a rebate such that the net cost to the provider to acquire the drug equals average sales price + 3 percent minus a standard overhead fee to be determined by the

Secretary. This rebate would not be used in calculating average sales price. The Secretary would also be given authority to pay a portion or the entire amount above average sales price in the form of a flat fee rather than a percentage, with the modification to be made in a budget neutral manner relative to average sales price + 3 percent.
Estimated Savings: $7.4 billion over 10 years

Reforming Medicare Physician Payments to Encourage High-Quality, Efficient Care
The Budget accelerates physician participation in high-quality and efficient health care delivery systems by repealing the Medicare Sustainable Growth Rate (SGR) formula and reforming Medicare physician payments in a manner consistent with the reforms included in recent bipartisan, bicameral legislation.
Estimated Cost: $44 billion over 10 years

To view the President's FY2016 Budget Proposal, CLICK HERE.

To view an overview of the Budget, CLICK HERE.

Obama Administration Releases Details of Precision Medicine Initiative

During his 2015 State of the Union Address, President Obama announced a new Precision Medicine Initiative that will help deliver the right treatment to the right patient at the right time. The White House has released additional details regarding the research program, which it hopes will revolutionize how the U.S. improves health and treats diseases.

Precision medicine – also referred to as personalized medicine – specifically utilizes individualized genetic mapping to provide targeted care to patients. The practice is already widely utilized in the treatment of certain forms of cancer.

Key objectives identified by the Administration for the Precision Medicine Initiative include:

- More and better treatments for cancer
- Creation of a voluntary national research cohort
- Commitment to protecting privacy
- Regulatory modernization
- Private-public partnerships

Specific to cancer treatments, the program will add funding to the National Cancer Institute (NCI) to, "accelerate the design and testing of effective, tailored treatments for cancer by expanding genetically based clinical cancer trials, exploring fundamental aspects of cancer biology, and establishing a national 'cancer knowledge network' that

will generate and share new knowledge to fuel scientific discovery and guide treatment decisions."

The President's Budget released this week also includes $215 million in funding to launch the initiative, which will accelerate the nation's ability to develop prevention, diagnostic and treatment approaches tailored to individual patients.

An additional $130 million of the initiative's total funding will go to the National Institutes of Health (NIH) to identify and track the DNA sequences of one million volunteer donors. Another $70 million will be dedicated the National Cancer Institute, which is part of the NIH, to bolster biomedical innovation in personalized medicine.

The final $15 million will go to the Food and Drug Administration (FDA) and Office of the National Coordinator (ONC) in order to establish policies to accelerate approval for DNA sequencing technology and protect patient privacy.

According to the President's Budget, the proposed funding will "catalyze key components of the Precision Medicine initiative through initial investments in the establishment of a national research group of a million or more Americans, expansion of research to define cancer subtypes and identify new therapeutic targets, accelerated development of promising new DNA-sequence-based diagnostic tests, and enhancement of interfaces for electronic health records and patient-generated data in assessment of individual health and population-level trends."

To read the White House Fact Sheet, CLICK HERE.

21st Century Cures Initiative Enters Legislative Phase

On January 27, the House Energy and Commerce Committee released draft legislation identified as a "discussion document," which outlines specific proposals that have been shared with Congress since they launched the 21st Century Cures Initiative last year.

Policies included in the discussion document include:

- Require CMS to analyze and seek public input on how proposed Medicare pay policies affect provider and payer consolidation
- Create maximum out-of-pocket costs, including deductible and cost sharing, for Part B Medicare beneficiaries
- Clarify the Continuing Medical Education Sunshine Act exemption

In releasing this initial outline of legislative ideas, the E&C committee is seeking additional feedback on the proposals and urging others to share ideas that could benefit patients who are struggling with diseases today. The committee aims to introduce a 21st Century Cures bill this year that can ultimately be sent to President Obama's desk.

To view the Energy and Commerce Committee press statement, CLICK HERE.

To view a section-by-section outline of the discussion document, CLICK HERE.

To view the discussion document one-pager, CLICK HERE.

On January 29, Senate Health, Education, Labor and Pensions (HELP) Committee Chair Lamar Alexander (R-TN) and Senator Richard Burr (R-NC) released a report on the challenges to getting safe treatments, devices and cures to patients more quickly and effectively, which closely mirrors the goals of the 21st Century Cures Initiative. In the report, the Senators identified five themes for improving the quality of life and outcomes for American patients:

1. It costs too much to bring medical products through the pipeline to patients.
2. As science and technology advance, the discovery and development process takes too long for medical products to make their way to patients.
3. FDA's responsibilities have grown to include many activities unrelated to the core function of regulating medical products to advance the public health.
4. The disparity in scientific knowledge at FDA and the fast pace of biomedical innovation are slowing, and in some cases, stifling innovation in American medicine.
5. A working FDA is essential to continuing biomedical innovation in the United States and maintaining America's global leadership in medical innovation.

The Senators are also seeking input and ideas from healthcare stakeholders to support the development of a bipartisan legislative package to address the challenges above.

To read the Senate report, *Innovation for Healthier Americans*, CLICK HERE.

HHS Unveils Plan to Revamp Medicare Payments

The Department of Heath and Human Services (HHS) outlined a broad plan this month to incentivize quality over quantity in Medicare payments.

The proposal would overhaul the traditional fee-for-service payment model in place for standard Medicare beneficiaries, reimbursing doctors based on patient outcomes rather than services provided. Specifically, the Obama Administration seeks to:

- **Increase the amount of payments tied to quality or value-based payment models.** *According to its plan, HHS would tie 85% of reimbursements to patient outcomes by 2016. The number would then move to 90% by 2018.*

- **Expand Medicare benefits linked to alternative payment models.** *HHS would tie 30% of traditional Medicare payment models, such as Accountable Care Organizations (ACOs) by next year. The number would then move to 50% by the end of 2018.*

Ultimately, HHS hopes the new policy will improve care and reduce costs as providers "have a financial incentive to coordinate care for their patients – who are therefore less likely to have duplicative or unnecessary x-rays, screenings and tests."

"Whether you are a patient, a provider, a business, a health plan, or a taxpayer, it is in our common interest to build a health care system that delivers better care, spends health care dollars more wisely and results in healthier people," HHS Secretary Sylvia Mathews Burwell said in a statement. "We believe these goals can drive transformative change, help us manage and track progress and create accountability for measurable improvement."

HHS also announced the creation of the Health Care Payment Learning and Action Network, which will aim to expand value-based payment to additional sectors of the health insurance market, including employer-based coverage and state Medicaid programs. The Network will hold its first meeting in March of 2015.

For the official HHS release, CLICK HERE.

HHS Asks DC Court To Drop 340B Orphan Drug Lawsuit

The U.S. Department of Health and Human Services (HHS) reportedly asked a D.C. federal court on January 27 to drop the lawsuit from the Pharmaceutical Research and Manufacturers of America (PhRMA) challenging an HHS rule that requires drug manufacturers to offer 340B program discounts for orphan drugs used to treat non-rare conditions at certain covered entities under the 340B program.

In May 2014, a federal court ruled that the agency did not have rule-making authority to regulate the 340B program. At issue is an Affordable Care Act (ACA) provision that made additional types of hospitals eligible for 340B, but prevented them from getting deep discounts on drugs designated for treating a rare disease or condition when treating non-rare diseases.

In response, the Health Resources and Services Administration (HRSA) – and arm of HHS – released an interpretive rule on the orphan drug exclusion that allows for discounts for non-orphan uses of orphan drugs. HRSA has indicated it will penalize drug manufacturers that withhold discounts on the orphan drugs when used to treat common conditions.

PhRMA then filed another lawsuit asking the court to rule whether the HRSA final rule can be upheld as an interpretive rule or if the rule could be vacated because HRSA lacks the proper rulemaking authority.

HRSA claims its interpretation of the statute is consistent with Congress' intention of rewarding drug makers for developing orphan drugs while saving health care providers money.

The court is not required to take action until HRSA penalizes a drug maker for failing to comply with the statute.