

**Morgan Lewis**

***FAST BREAK:***

# **21ST CENTURY CURES ACT**

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# Today's Fast Break ...

- Cures Act provisions that represent greatest innovation enhancements for pharmaceuticals
- Realities of implementation challenges to Cures Act
- Overview of Medicare and Medicaid Provisions

# Fast Facts on 21st Century Cures

- Developed over several years, the broad Cures Act represents many “fixes” to multiple challenges facing the healthcare industry
- Developed slowly, passed quickly.
- Congress passes December 7 with strong bipartisan support, President Obama signs into law December 13, 2016
- Effective and key implementation dates vary; regulatory action and guidance from agencies will be necessary for implementation in many areas.

# Environment for Rollout - The Uncertainty Principle?

- Environment in Washington
  - GOP in control of House, Senate, and White House
  - Ambitious Agenda for New Congress/Administration
  - Divisive atmosphere
- The uncertainties impacting HHS Implementation
  - Agencies in leadership transition
  - Budget constraints
  - Executive Order on Reducing Regulation and Controlling Regulatory Costs
  - Presidential Memorandum Regarding the Hiring Freeze, reduction by attrition
  - Presidential Memorandum on Regulatory Freeze Pending Review – applies to regulations/guidance

# 21st Century Themes

- With ambitious goals, the Cures Act is intended to spur development of therapies; facilitate review and approval processes for innovative products; and modernize the delivery of healthcare services.
- Recognition of fast developing technologies/science and intersection with regulatory hurdles
- Cures Act also aims to increase transparency
- Moving on to innovation.....

# Cures Act Focus on Novel Research

- NIH will be funding research in:
  - Novel approaches to cancer treatment (e.g., vaccines, immunotherapy, biomarkers, combination therapies)
  - Brain research
  - Precision Medicine
  - Regenerative Medicine
  - Drug discovery and streamlining processes that can assist in expediting product approval
- New research dollars will cause some shifting of private and public financial and scientific resources to these areas and regulations
- Could be a scramble for the NIH funds, especially for smaller companies
- Easing of NIH constraints around its money will make it more attractive as a partner
- NIH involvement in clinical trials through Phase 2B for rare diseases may create new opportunities and challenges
- Reinvigorated OMB review with its Research Policy Board Advisory Committee will provide an outlet for regulatory over-reach or delay

# Cures Act Focus on Speed to Market

- Use of Real World Evidence and Patient Experience Data to support product approvals
- Initial discussions between FDA and industry will involve how to collect / validate data; companies will need to push for early adoption and coordinate with patient groups and researchers
- Development and use of new drug development tools and process for review presents challenges and opportunities
- Pediatric vouchers for rare diseases and BARDA vouchers for countermeasure drugs should spur development in these targeted areas

# Cures Act Focus on Targeted Interests

- Regenerative Medicine
  - FDA already issued guidance for a RAT designation
- Antimicrobials
- Vaccines
- Medical countermeasures
  - BARDA authority for partnering clarified
  - Establishes a priority review voucher for development of drugs and vaccines for threats to national security (Sunsets 2023)



# Cures Act Focus on Healthcare Economic Information (HEI)

- Consistent with recent PhRMA code changes that encourage HEI submissions to payors
- Expands universe of audience to “payors, and similar entities with knowledge and expertise in the area of HEI, carrying out its responsibilities for the selection of drugs for coverage or reimbursement.”
- May directly or indirectly relate to approved indications
- Must be based on competent and reliable scientific evidence, and disclosure of material differences between HEI and approved labeling
- Applies to drug, biologics, biosimilars

# HEI

- Broad definition of HEI
  - Analysis
  - Identifies, measures, or describes
  - Economic consequences
  - Based on separate or aggregated clinical consequences of the health outcomes from use of the drug
  - Allows for broad comparisons of therapies – others, drug, interventions, or no intervention
- Distribution of HEI requires no implementing action by FDA
- Will support risk-sharing or performance-based selection and maintenance agreements between pharma companies and insurers
- May generate new types of entities who create and disseminate HEI on behalf of drug companies

# Open Questions

- How will FDA prioritize guidances and stakeholder meetings in era of 3 R's:
  - Republican agenda
  - Regulatory reform
  - Reduced personnel
- What will industry (BIO, PhRMA, GPA, Biosimilars Council) prioritize?
- How will patient groups influence the priorities?

# 21st Century Act – Mental Health & Substance Abuse

- Cures Act includes many elements from earlier proposed legislation (e.g., Helping Families in Mental Health Crisis Reform Act), builds on the Mental Health Parity and Addiction Equity Act of 2008 and Affordable Care Act essential health benefit requirements
- Cures Act includes provisions impacting health plans, research grants, public health measures, Medicaid program issues, and also addresses law enforcement
- Requires HHS, DOL and Treasury to develop compliance guidance for health plans to address behavioral health limits
- Allocates funding (\$1B over 2 years) to assist states fighting opioid and heroin abuse
- Implementation challenges?

# 21st Century Act – Hospitals

- Cures Act provides much needed relief from the requirements imposed in the Bipartisan Budget Act (BiBA) of 2015 that prevent Medicare OPPS payments furnished in new outpatient facilities not on a hospital's campus after 1/1/17
- Extends grandfather protection to a narrow subset of “mid-build” projects
  - Providers that submitted attestation prior to 12/2/15; or
  - Providers who had a “binding written agreement” for “actual construction” as of 11/2/15
- Uncertainty remains in definition details
- Providers citing “mid-build” exception must file attestation immediately

# 21st Century Act – Hospitals

- Hospital Inpatient Short Stays – new HCPCS codes for 10 surgical MS-DRGs with one-day length of stay
- Hospital Readmissions Reduction Program- CMS to develop “groups” of hospitals based on (initially) proportion of dual eligibles served by the hospital
- Document and Coding Payment Adjustments –slight downward adjustment for 2018
- LTAC – “25 percent rule” enforcement suspended for FY 2017 along with other new LTAC policies and technical changes

# 21st Century Act – Other providers

- ASCs/Physicians – Prohibits CMS from penalizing physicians (under the Meaningful Use Program or the future MIPS) who furnish “substantially all” of their Medicare-covered professional services in an ASC
- DME – Cures Act delays (again) application of the competitive bidding program (CBP) ceiling payment rates for accessories furnished in connection with complex rehab technology power group three wheelchairs for 6 months
- DME - Delays application of CBP ceiling payment to areas not in CBP
- DME – Moves up caps on Medicaid payments to 1/1/2018 (offset)

# 21st Century Act – Other providers

- Physical Therapists - Allows PTs furnishing OP PT services in a HPSA, medically underserved area or a rural area to use specified locum tenens arrangements in the same manner as physicians subbing for other physicians
- Infusion Therapy – New Medicare coverage for home infusion therapy, Cures Act defines qualified suppliers and “home infusion drug” and HHS to develop payment system
- Changes to the process for assigning beneficiaries under the Medicare Shared Savings Program beginning on or after 2019



# 21st Century Act – Medicare Advantage

- Beginning in 2019, Cures Act requires CMS to implement changes to the risk adjustment methodology
- Beginning in 2021, Medicare beneficiaries with end-stage renal disease (ESRD) will be able to enroll in Medicare Advantage Plans
- Cures Act postpones CMS' ability to terminate contracts with Medicare Advantage plans that don't achieve at least 3 Stars until plan year 2019
- Enrollment provisions:
  - HHS to submit detailed MA enrollment data to Congress
  - CMS to update the "Welcome to Medicare" package
  - Restores (with a few tweaks) the previous 3 month approach to the Medicare Advantage open enrollment process

# 21st Century Act – Telehealth

- Cures Act does not change existing Medicare requirements related to telehealth, **but...**
  - Directs CMS to report to Congress on:
    - Potential uses of telehealth for Medicare beneficiaries;
    - Where telehealth could improve clinical care; and
    - What impediments currently exist that prevent expansion of Medicare telehealth coverage.
  - Directs MedPAC to report to Congress on:
    - Current disparity between Medicare and private insurers in terms of telehealth coverage; and
    - How parity between Medicare and commercial payors can be achieved.
- Focus is on “originating sites” and expansion of rural limitations

# 21st Century Act – Medicare Improvements in Transparency

- Local Coverage Determinations (“LCDs”) – MACs will need to develop LCDs through a more transparent process including a requirement to post the LCD online 45 days before effective date
- CMS to have a “Pharmaceutical and Technology Ombudsman” to address complaints, grievances, and requests from manufacturers of pharmaceutical, biotech, medical device, or diagnostic products regarding coverage, coding, or payment issues
- CMS to develop a searchable website for Medicare beneficiaries to determine payment amounts for hospital outpatient departments vs ASC payment amounts and the beneficiary liability for items and services provided in each setting

# 21st Century Act – Fraud & Abuse

- New OIG CMP Authority for Violations of Grants, Contracts, and Other Agreements
- Significant new Federal/State Coordination on Medicaid Provider Enrollment and Termination including:
  - States and MCOs required to report provider terminations
  - New national, centralized database on providers
  - Implementing centralized enrollment standards
  - Mechanisms for improving communications

# 21st Century Act – Additional materials

- [21st Century Cures Act and Its Effect on Digital Health](#) – Michele Buenafe, Elizabeth Bierman
- [21st Century Cures Act and Medical Device Regulatory Pathways](#) – Michele Buenafe, Elizabeth Bierman
- [21<sup>st</sup> Century Cures Act's Effect on Pharmaceutical and Biotechnology Industries](#) – Kathy Sanzo, Stephen Mahinka
- [21st Century Cures Act: Who Does the "Mid-Build" Exception Help?](#) – Andy Ruskin, Eric Knickrehm
- [Small Employer HRAs –A New Year's Gift](#) – Jeanie Cogill
- [21st Century Cures Act Benefits Biopharma Co. Data Use, \*Law360\* Publication](#) – Kathy Sanzo, Stephen Mahinka

# Thanks!



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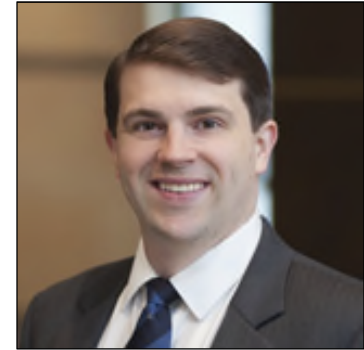
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