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*May 2010 Health Care Reform Update*



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Kathleen M. Sanzo, Esq.  
[Ksanzo@morganlewis.com](mailto:Ksanzo@morganlewis.com)

Washington, DC

# Healthcare Reform Themes

- Although there are a number of states and other groups challenging the constitutionality of the law, HHS and others are forging ahead with implementation.
- Implementation will take a massive effort and the full impact will not be known for at least a decade.
- More than 9 federal agencies will be involved in the implementation and over 500 (estimated) rules will need to be written, proposed, and finalized.

# Healthcare Reform Themes (cont'd)

- Although drug and device companies are not the focus of HCR, they will feel the impact directly, and indirectly through their customers.
- Strategic plans will need to be adjusted to account for the new short term and long-term economic order under HCR
  - Who will be the customers? Federal government, state insurance exchanges, private plans, comparative effectiveness committees, practitioners, hospitals, nursing homes?
  - What will the government pay for your product?
  - What are the new drivers for product value now, and in four or ten years?
  - How do you adjust your product development timeline to account for the new value drivers?

# Healthcare Reform Themes (cont'd)

- What are the health outcomes quality metrics that will be used to judge your product? Reduced disease, hospital readmission, re-infection rates, disease markers?
- How will new quality metrics drive the value-added services that the product supplier will be expected to provide? Additional funded research, more data, bundled pricing for generic and branded drugs and biologics?
- What kind of new compliance issues will be raised by these new demands?

# Healthcare Reform Provisions with Direct Impacts on Drug and Device Companies

- Tax credit or grants/CAN research grants
- Follow-on biologics pathway
- Clinical trial coverage
- Comparative effectiveness research provisions
- Drug access provisions
- Drug cost and pricing provisions
- Drug and device fees
- Transparency requirements

# Tax Credits/ Cash Grants

- Tax credit or equivalent cash grant for small businesses making “qualified investments” in “qualified therapeutic discovery” project in 2009/2010.
- Benefit capped at \$1B.
- IRS will announce program by May 22, 2010.
- IRS makes determinations with consultation with HHS.
- Biotech industry lining up to get credit/cash.
- Do not know whether IRS will reserve a pool to fund later projects.

## Tax Credits/ Cash Grants (cont'd)

- “Qualifying investments” for “qualifying therapeutic discovery” includes:
  - Pre-clinical or clinical research for new drugs
  - Molecular diagnostics, affecting therapeutic decisions
  - Drug delivery or administration technologies
- Reasonable potential to treat unmet need; or treat acute or chronic diseases, or
- Reduce long term healthcare costs, or
- Advance cures for cancer.
- Sustain high paying U.S. jobs and advance U.S. competitiveness in the product area.

# Cures Acceleration Network (CAN)

- Administered by NIH.
- Awards grants and contracts to private and government groups.
- Directed to basic research and high need cures (e.g., orphan drug-type products) through products or behavioral therapies.
- Grants may not exceed \$15M per project per year.

# Clinical Trial Coverage

- Health plans cannot deny coverage of certain routine patient costs for participating in approved clinical trials for cancer or life-threatening diseases.
- Does not cover clinical drug supply.
- Likely will affect negotiation of clinical trial budget and agreements.

# Follow-On Biologics Pathway

- Innovator biologics receive 12 years of exclusivity for first approval; no exclusivity for sBLAs or new indications, dosing, administration, delivery system, etc of the reference product, or modifications that do not affect the safety, purity or potency of the reference product
- Law establishes an abbreviated licensure pathway (351(k) applications) for biosimilar biologics
  - 351(k) applications cannot be accepted by FDA for at least 4 years after the date on which the reference product (RLD) was first approved
  - User fees for approval of follow-on products starting 2012
- There is first biosimilar exclusivity

## Follow-On Biologics Pathway (cont'd)

- Biosimilar defined as:
  - Product is highly similar to the RLD
  - There can be only one RLD
  - There are no clinically meaningful differences between the biosimilar and the RLD in terms of safety, purity, and potency of the product
- Interchangeable means the biosimilar may be substituted for the RLD without intervention of HCP

## Follow-On Biologics Pathway (cont'd)

- Biosimilar applicant must establish biosimilarity through:
  - Analytical studies showing that the biosimilar is highly similar notwithstanding minor differences in inactive ingredients
  - Animal studies (including to show toxicity);
  - Clinical studies (including immunogenicity and PK and/or PD studies) that are sufficient to show safety, purity and potency in one or more conditions for which the RLD is approved.
- FDA can waive any of the above requirements.
- The applicant must also show that the RLD and biosimilar utilize the same MOA, if it is known.

## Follow-On Biologics Pathway (cont'd)

- The products are interchangeable if they are expected to produce the same clinical result as the RLD; and there is no additional safety risk presented by the possible switching between the RLD and the biosimilar.
- An interchangeable biosimilar should not be considered to have a new active, while a non-interchangeable would be considered to have a new active ingredient.
- The conditions of use for the biosimilar have been approved for the RLD.
- The route of administration, dosage form, and strength are the same.
- The manufacturing facility for the biosimilar meets standards which will assure that the biosimilar is safe, potent and pure.

## Follow-On Biologics Pathway (cont'd)

- There are separate rules for biosimilars for orphan drugs
- REMS authority applies to biosimilars
- FDA has authority to publish biosimilars guidelines but is not required to do so before approving biosimilars
- There are very complicated patent provisions, which amount to managed arbitration before patent litigation

## Follow-On Biologics Pathway (cont'd)

- There are very complicated patent provisions, which amount to managed arbitration before patent litigation
  - Biosimilar applicant must provide its application to the RLD holder
  - Only after RLD gets copy of 351(k) application does it provide a list of potential infringing patents
  - Complicated but short timelines for parties exchanging positions on patent status and patent challenges

## Follow-On Biologics Pathway (cont'd)

- Transition Products (e.g., biologics approved as drugs)
  - Can continue to submit NDAs for these types of products for 10 years
  - Unless there is a 351(k) that could be a RLD
  - Previously approved NDAs shall be deemed a BLA as of March 2020

## Follow-On Biologics Pathway (cont'd)

- FDA just announced appointment of Dr. Leah Christl as Acting Associate Director for Biosimilars.
- Dr, Christl has her Ph.D. in Molecular and Cellular Biology and Pathobiology - Marine Biomedicine and Environmental Science from the Medical University of South Carolina in Charleston.
- Office of New Drugs is setting up a Biosimilars Review Committee to serve in an advisory capacity to OND reviewing divisions on questions relating to biosimilar product development.

# Comparative Effectiveness Research Provisions

- Law provides for research on comparative effectiveness (CER) through Patient Centered Outcome Research Institute (PORI)
- Law prohibits CMS from using comparative effectiveness to determine coverage and reimbursement or create practice guidelines.
- Law does not address use of CER by insurance plans or exchanges
- Government considering its own form of academic counter-detailing using CER
- Wellpoint already creating new guidelines on how to submit CER to its P&T committee

# Drug Access Provisions

- HCR reduces Medicare Part D beneficiary co-insurance coverage gap
  - By 2020, beneficiary co-insurance for branded drugs reduced from 100% to 25%
    - Brand name drug manufacturers will be required to offer 50% discount to beneficiary at POS for its drugs, effective 2011
    - Discount will be a requirement to have drugs covered under Part D program
    - DHHS must issue a model agreement within 6 months of enactment
  - By 2020, beneficiary co-insurance for generic drugs reduced from 100% to 75%
    - Phase-in commences 2011
  - \$250 coverage gap rebate (administered quarterly), effective for 2010
  - Increase initial coverage limit by \$500, effective for 2010

# Cost and Pricing Provisions

- Changes to Medicaid drug rebates, effective 1/1/2010
  - Basic rebate for “S” and “I” drugs (generally “branded” and authorized generic products) increased to 23.1% of AMP (from 15.1%)
  - Clotting factor and exclusively pediatric indications to 17.1% of AMP (from 15.1%)
  - Basic rebate for “N” drugs (generally “generic” products) increased to 13% of AMP (from 11%)
  - Additional rebate for new formulations of “Oral Solid Dosage Form” products
- Extends Medicaid drug rebates to Medicaid MCOs, effective 3/23/2010

# Cost and Pricing Provisions (cont'd)

- Re-defines AMP, effective 10/1/2010 to more accurately reflect retail pharmacy acquisition cost
  - Average price paid to the manufacturer for the covered outpatient drug in U.S. by (1) wholesalers for drugs distributed to retail community pharmacies; and (2) retail community pharmacies that purchase drugs directly from the manufacturer
  - More limited definition than the current regulatory definition that includes, among other things, hospital outpatient sales, mail order pharmacy sales, physician sales, LTC and various other purchasers
  - Note – retail does not include mail order, hospital or LTC pharmacies
- Requires public disclosure by DHHS on web of weighted average of AMP for multi-source drugs only, effective 10/1/2010
  - NACDS injunction may delay publication until December at earliest

# Cost and Pricing Provisions (cont'd)

- Changes the 340B outpatient drug discount program
  - Expands participation to additional purchasers including cancer hospitals, certain children's hospitals, critical access and sole community hospitals and rural referral centers
    - These additional purchasers do not appear to be subject to GPO purchasing restrictions
  - Does not include expansion to any inpatient purchases
  - Adds “integrity” provisions for manufacturers and covered entities
    - Among other items, manufacturers must refund for overcharges
  - Adds a “must sell” provision and reporting obligations

## Cost and Pricing Provisions (cont'd)

- Changes to Medicaid outpatient FFS drug reimbursement for generics known as FULs, effective 10/1/2010, among other things:
  - FULs for multiple source drugs if 2 or more equivalent products in class (e.g., 3 or more drugs) shall be “no less than” 175% of the weighted average (based on utilization) of the most recently reported monthly AMPs for the group of equivalent products “that are available for purchase by retail community pharmacies on a nationwide basis”

# Drug and Device Fees

- Imposes an annual fee, which is not tax deductible, on pharmaceutical manufacturers of branded prescription drugs
  - Fee imposed on manufacturers and importers
    - “Importers” not defined
  - Other fees imposed on insurers (effective 2014, \$8 billion industry fee allocated on market share, with certain rules for nonprofits and others)
  - Medical device manufacturers (effective 2013, a 2.9% excise tax on taxable medical devices, with certain exceptions)
- Total fee of \$2.5 billion divided among the industry for 2011
  - Increases to \$4.1 billion by 2018
  - Drops to \$2.8 billion from 2019 forward
- Tax is imposed relative to share of annual sales “to any specified government program”
  - Medicare Parts B and D, Medicaid, VA, DoD, TRICARE

# Transparency Requirements

## Physician Payment Sunshine

- Applies to any value of \$10 or more or any value of \$100/year.
- First report covers payments made in 2012.

## Exclusions

- Product samples
- Educational materials
- Device loaners
- Warranty replacements
- Only applies to manufacturers who have products for which “payment is available” under Medicare, Medicaid, or SCHIP.

## Transparency Requirements (cont'd)

- Applies to payments for research or education but they do not have to be disclosed until drug/device approved or 4 years after payment, whichever is earlier.
- Does not apply to “indirect” payments through third parties, unless sponsor can influence selection of HCP.
- Preemption provision allows for stricter state laws on reporting or those state laws requiring different information or data.

## Transparency Requirements (cont'd)

- Samples Reports—by number and practitioner requesting
- PBMs must report rebates, discounts, price concessions given by suppliers; retail vs. mail order prescription drug sales; percentage of prescriptions for which generics are available

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