# US Regulatory and Reimbursement Issues for Life Sciences Companies

*Michael J. Werner*

*Partner, Holland & Knight*

***August 1, 2017***

Holland & Knight

# About Holland & Knight

- Global law firm with more than 1,200 lawyers and other professionals
- 24 U.S. offices, as well as Bogotá, Mexico City and London
- Representation in business, litigation, real estate and governmental law
- Over 100 Interdisciplinary practice groups and industry-based teams that provide clients with access to attorneys throughout the firm, regardless of location.

# Holland & Knight Offices


Holland & Knight

# About Holland & Knight

- 2016 BTI Consulting Group's annual survey of corporate counsel and C-level executives recommends Holland & Knight for 5 years in a row in the leading 25 top-performing law firms providing superior client service; and was also named to the 2016 BTI Client Service A-Team (December 2015).
- Received national first-tier rankings in the 2016 U.S. News – Best Lawyers® "Best Law Firms" guide in 35 practice areas. The firm was also named "Law Firm of the Year" in the areas of Admiralty & Maritime Law and Native American Law (November 2015).
- 302 lawyers representing more than 80 different practice areas were named Best Lawyers in America in the 2016 guide (August 2015).
- The firm secured six practice area rankings by Legal 500 United States and 25 individual lawyer recommendations (July 2015).
- More than 140 Holland & Knight attorneys were named "America's Leading Lawyers for Business" in the Chambers USA 2015 guide (May 2015).

# Overview of Life Science Practice

- Extensive experience includes the development and execution of integrated strategies that leverage its regulatory and reimbursement skills to enable companies to develop, manufacture, market and distribute medical devices, prescription drugs, biologics, biosimilars, combination products and over-the-counter (OTC) drugs.
- H&K literally "wrote the book" on these issues as it authored the Bloomberg BNA portfolio "Life Sciences Compliance: A Pre-Market and Post-Market Road Map."
- Legal experience essential to dealing effectively, throughout a product's life cycle, with today's increasingly complex regulatory and policy challenges, many of which are driven by the U.S. Food & Drug Administration (FDA), as well as reimbursement issues such as those before the Centers for Medicare and Medicaid Services (CMS).
- Deep connections within the industry and its significant legal practice.

# FDA Regulatory Practice

- Rx drugs, over-the-counter (OTC) drugs, biologics, biosimilars, medical devices, supplements, food, etc.
- Assist clients:
  - understand FDA requirements
  - design, develop and implement regulatory pathway strategies for success
  - remain or come into compliance with the FDA's post-market obligations
- Provide real-time analysis of FDA regulations to help companies plan their clinical programs
  - create or review a company's policies and procedures to ensure compliance with regulations and consistency with industry best practices

# H&K FDA Regulatory Practice

- Perform “regulatory due diligence” for investors in biotechnology and medical device companies
- Advise clients on their strategies for filing Investigational New Drug applications, 510(k)
- Negotiate terms of clinical trial agreements with research institutions and investigators
- Negotiate the regulatory pathway to market for novel technologies
- Resolve disputes with FDA regarding clinical trial requirements to support a premarket approval (PMA) Supplement
- Counsel and represent companies before the FDA on voluntary recalls
- Represent clients during inspections and post-inspection matters, including responses to Form 483s, untitled and warning letters
- Establish compliance plans
- Support manufacturers seeking GRASE determinations for over-the-counter drugs
- Advise on medical claims for labeling and marketing
- Represent industry trade associations in FDA negotiations

# Reimbursement Needs of Life Science Companies

- Our team serves all of the public and private sector reimbursement needs of life sciences companies
  - Work with CMS and its Medicare Administrative Contractors to modify or develop local or national coverage policies
  - Develop and execute coding, coverage and payment for products
  - Physician fee schedules and payments
  - Ambulatory surgery center (ASC) payments
  - Hospital outpatient and inpatient payment systems, including applying for and obtaining pass-through status for qualified technologies

# Regulatory Environment

- Very positive and supportive of innovation
- FDA looking to revise its procedures to modernize and more efficient
- Enable new products to reach patients as soon as possible
- Promote competition
- Comprehensive approach – drugs, biologicals, devices

# FDA's New Initiatives

- Comprehensive Innovation
  - Implementation of "21st Century Cures Act"
  - Drugs and Device provisions
- Generic Drugs
- Digital Health
- Orphan Drugs

# Innovation Initiative – 21st Century Cures Act

- Implementation plan:

https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCAct/21stCenturyCuresAct/ucm562475.htm

- Regenerative Medicine – RMAT implementation; new guidance; standards
  - RMAT allows RM products to qualify for expedited review programs (priority review, etc.);
  - Cell-based products so far
- Device regulation – CDRH has exempted 70 Class I device types from 510(k) process and proposed exempting many Class II devices from 510(k) submission. Also more devices will qualify for humanitarian use exemption.
- Patient-focused drug development – Guidance re: systematic approach to using patient perspectives

# Generic Drugs

- Priority issue – seen as way to reduce Rx drug costs
- Drug Competition Action Plan
  - Revise priority review process to allow prioritized review of generic drug applications until there are 3 approved generics for a product.
    - Data suggests consumers get price reductions when there are at least 3 generics
  - Publication of list of off-patent, off-exclusivity drugs for which there is no FDA approved generic
    - Continuously updated

# Digital Health – 21st Century Cures Act

- Exempts from FDA regulation certain medical-related software, including software used for administrative support functions at a healthcare facility, software intended for maintaining or encouraging a healthy lifestyle, and electronic health record (EHR) software. Also software for transferring, storing, converting formats, or displaying clinical lab test data and results.
- Clinical decision support (CDS) software: displaying, analyzing, or printing medical information; supporting or providing recommendations to a healthcare professional about prevention, diagnosis, or treatment of a disease or condition; and enabling the healthcare professional to independently review the basis for such recommendations.
- Limitations: Software with these functions will be subject to medical device regulations if FDA finds that such software would be "reasonably likely to have serious adverse health consequences". Factors FDA considers are:
  - The likelihood and severity of patient harm if the software were to not perform as intended; the extent to which the software function is intended to support the clinical judgment of a healthcare professional;
  - Whether there is a reasonable opportunity for a healthcare professional to review the basis of the information or treatment recommendation provided by the software function; the intended user and user environment

# Digital Health

- FDA has already said that certain digital health technologies—such as clinical administrative support software and mobile apps that are intended only for maintaining or encouraging a healthy lifestyle—generally fall outside the scope of FDA regulation. New guidance:
  - Mobile medical applications;
  - Medical device data systems, used for the electronic transfer, storage, display, or conversion of medical device data;
  - Medical image storage devices, used to store or retrieve medical images electronically;
  - Medical image communications devices, used to transfer medical image data electronically between medical devices;
  - Low-risk general wellness products; and
  - Laboratory workflow
- Guidance on clinical decision software in Q1 2018

# Digital Health

- On July 27, FDA announced new pilot program to evaluate a “new approach toward software products, including a precertification program for the assessment of companies that perform high-quality software design and testing.”
- FDA will develop the program for developers to replace the need for a premarket submission in some cases and allow for decreased submission content and/or faster review of marketing applications for software products in other cases. During the pilot program, FDA customers can provide input on the development of the precertification program.
- Certification could be used to assess whether a company "consistently and reliably" engages in high quality software design and testing as well as ongoing maintenance of its software products.
- Applications due starting Aug 1

# Orphan Drugs

- Plan to reduce backlog of orphan drug requests
- Currently about 200
- FDA promises to prioritize review of those older than 120 days and then will review all requests within 90 days
- Establishing a SWAT team

# Reimbursement – Several CMS Proposals in Play

- Pricing pressures for life sciences but not likely any dramatic proposals

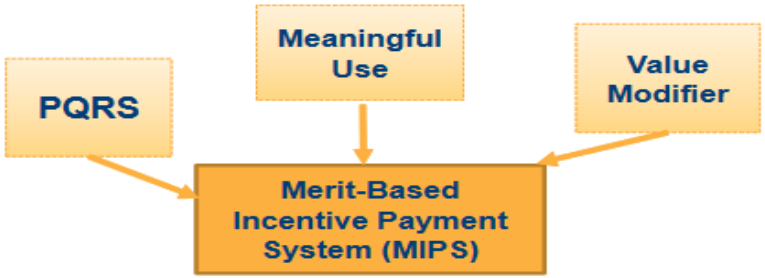
- MACRA (physician payment)
- Payments for new technologies used as part of in-patient procedure
- Payments for biosimilars

# MACRA: Three Main Components to SGR Replacement

## 1) Predictable Updates

- Repeals SGR formula
- 0.5% update through 2019
- 0.0% update through 2020-2025
- 2026 and beyond, two conversion factors:
  - 0.75% update for Qualifying APM
  - 0.25% for all others

## 2) New Consolidated Pay-for-Performance Program




- Performance based on quality, resource use, clinical practice improvement activities, and meaningful use of EHRs (starting 2019)
- Does not apply to low-volume providers, qualifying APM participants, and partial qualifying APM participants (that did not report the necessary information.)

## 3) Alternative Payment Models (APM) Incentives

**Qualifying APM Participant**

- Significant participation in APM
- Eligible for bonuses (2019-2024)
- Higher update starting 2026
- Avoid MIPS

**Partial Qualifying APM Participant**

- Slightly lower threshold for participation
- No bonus
- Might avoid MIPS
- Lower annual update

# Choose Your Own Adventure under the Quality Payment Program (QPP)

» MIPS Versus Advanced APMs

| | |
|---|---|
| "Merit-based Incentive Payment System" (MIPS) | • Eligible clinicians scored on quality, resource use, clinical practice improvement, and EHR use - and assigned a payment adjustment accordingly<br>• Reimbursement of +/- 9% when fully implemented |
| Advanced Alternative Payment Models | • Requires significant share of patients and or revenue in arrangements with nominal risk, quality measurement and EHR requirements<br>• Exempt from MIPS and qualify for a 5 percent incentive payment in 2019-2024 |

# MACRA Implications:

**"MACRA is to care delivery reform what the ACA was to coverage reform."**
***Andy Slavitt, former CMS Acting Administrator***

- APMs and MIPS will increasingly influence care patterns in favor of treatments that improve downstream clinical, financial, and patient-reported outcomes. Industry can help physicians understand the programs, their options, and how their products fit into the value equation.
- Manufacturers may want to better understand the methodologies linked with the identified Advanced APMs to determine how they will affect patient access to innovative treatments and devices, expensive therapies, and specialized care.
- The increasing number of qualifying Advanced APMs showcases CMS' intent to transition a majority of clinicians to APMs, this is especially relevant to specialty clinicians.
- Manufacturers need a strategy to take advantage of MACRA incentives as most US physicians will be paid under this system eventually

# New Technology Add-On Payment

- Designed to bridge the gap between the entry of an innovative new technology on the market and the incorporation of the cost of that technology into the MS-DRG system
  - Medicare pays CMS picks the lesser of two amounts, 50 percent of the amount by which the total covered costs of the case exceed the MS-DRG payment, or 50 percent of the costs of the new technology
- Must be “new” and show “substantial clinical improvement”
- CMS proposed rule says the new CAR-T from Kite doesn’t meet newness standard
- CMS final ruling this fall will impact reimbursement strategy for manufacturers

# Biosimilars Reimbursement

- CMS payment rule from 2015 says all biosimilars tied to same reference product receive a blended payment and single code.
- Inappropriately treats biosimilars as generic drugs and is dis-incentive for product development
- CMS proposed rule for 2018 seeks comment on whether the current policy will dampen competition and product development
- Final rule this fall will greatly impact the US market

# New Reimbursement Models?

- Pay for performance
- Annuity
- Re-insurance and risk pooling
- Implementation unclear and there are system barriers to overcome

# Congressional Actions

- Over-the-Counter Drugs
  - New user fee system being created
  - Already marketed products in tentative monographs become final
  - FDA must meet performance goals
  - New FDA approval pathway (with exclusivity) being created
  - Likely to be enacted this year
- User fee legislation for Rx drugs, generic drugs, medical devices, and biosimilars will be enacted
  - Keeps programs financially sound

# Conclusion

- Significant changes in US regulatory and reimbursement policy affecting life sciences companies
- Companies need to stay abreast of these developments and opportunities
- HK well-positioned to help you understand and navigate these changes to your benefit
- Happy to discuss a strategy

# Thank You!


Michael Werner

» Michael.Werner@hklaw.com

» +202-345-3668

» +202-419-2515