Medicare’s New Physician Payment System: What’s Now, and What’s Next:
Medicare Physician Payment Reform

May 18, 2015
MEDICARE’S NEW PHYSICIAN PAYMENT SYSTEM: WHAT’S NOW, AND WHAT’S NEXT

MEDICARE PHYSICIAN PAYMENT REFORM

May 18, 2015
7:00 – 8:00 p.m. ET

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MEDICARE’S NEW PHYSICIAN PAYMENT SYSTEM: WHAT’S NOW, AND WHAT’S NEXT

MEDICARE PHYSICIAN PAYMENT REFORM

May 18, 2015
7:00 – 8:00 p.m. ET

Agenda

7:00 – 7:45 p.m. Presentation

**Speakers:**
Paul M. Rudolf MD, *Partner, Arnold & Porter LLP, Washington, DC*


7:45 – 8:00 p.m. Question-and-Answer Session
Tab 2: Presentation
Medicare Physician Payment Reform

Paul Rudolf, MD, JD and Jen Madsen, MPH
Arnold & Porter LLP
May 2015

Agenda

- Context for Physician Payment Reform
- Overview of MACRA
- Two Pathways for Payment
- Your Options and Choices
Healthcare Spending as % of GDP*, 1965 - present

PROJECTION
2023
19.3%

COMPARISON
9% of GDP in UK, Iceland, Norway
12% of GDP in Austria, France, the Netherlands

* Gross Domestic Product

OVERVIEW OF MACRA
Congress Has Changed the Rules of the Game

- Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) became law on April 16, 2015
- Repeals the annual ~ 25% cuts from the Sustainable Growth Rate (SGR) formula
- Replaces SGR with a new Medicare payment system for physicians, nurses, physician assistants, and other health professionals
- Maintains focus on moving from volume to value

Projected Medicare Payments Prior to MACRA

1. Sustainable Growth Rate (SGR)
   -21.2% on April 1
   -25% or More
   -25% or More
   -25% or More
   2015 2016 2017 2018

2. Pay-for-Performance Penalties
   -4.5%
   -6%
   -9%
   -10% or More
Projected Medicare Payments WITH MACRA

1. Stable Conversion Factor (no more SGR)

<table>
<thead>
<tr>
<th>Year</th>
<th>Percentage Change</th>
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<tbody>
<tr>
<td>2015</td>
<td>-4.5%</td>
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<tr>
<td>2016</td>
<td>-6%</td>
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<tr>
<td>2017</td>
<td>-9%</td>
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<tr>
<td>2018</td>
<td>-10% or More</td>
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2. Pay-for-Performance Penalties STILL APPLY

Starting in 2019, Two New Pathways

New Pathway for 2019 +

- Physician Quality Reporting System (PQRS)*
- Value Based Modifier (VBM)*
- Meaningful Use of E.H.R.*

Alternate Pathway for 2019 +

- Alternative Payment Model (APM)

*3 Current Programs Sunset in 2018
TWO PATHWAYS FOR PAYMENT

Performance-Based Financial Risk Increases from +/-4% to +/-9%

- Phase-In of New System
- Risk Corridors of +/- 4 to 9%
- Budget Neutral (Sum = 0)
Merit-Based Incentive Payment System (MIPS)

- As a general rule, all physicians are eligible for MIPS.
- Physicians have an incentive to report all applicable MIPS measures.
- MIPS has four parts: quality, cost, meaningful use, and practice improvement.
- Physicians who do not report MIPS measures will receive low performance scores and negative payment updates.

In 2019 and 2020, CMS may adjust the weights within a range, from [resource use = 1% and quality = 59%] to [resource use = 10% & quality = 50% (2019)] and [resource use =15% and quality = 45% (2020)]

Further, if at least 75% of physicians are meaningful users of EHRs, CMS may decrease the MU weight to as low as 15% and re-weight the other categories as desired.
MIPS Composite Scoring System

Individual Performance in 4 Domains

- Clinical Practice Improvement
- MIPS Mean/median
- Resource Use
- Meaningful Use

Single Composite Score
0 to 100

Individual Composite Score Compared With Performance Threshold

Mean / Median Composite Score from Prior Year For All Physicians

Rate Adjustment Factor Based on Composite Score

<table>
<thead>
<tr>
<th>Year</th>
<th>Factor</th>
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<tbody>
<tr>
<td>2019</td>
<td>+4%</td>
</tr>
<tr>
<td>2020</td>
<td>+5%</td>
</tr>
<tr>
<td>2021</td>
<td>+7%</td>
</tr>
<tr>
<td>2022 and future</td>
<td>+9%</td>
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100% of Medicare Fee-For-Service Payment (RVU + CF)

In aggregate, MIPS adjustments are budget neutral.
Significant Incentive to Join APMs

- MACRA has $500 million annual bonus pool, 2019 – 2024
- Highest performers in MIPS (~top 12.5%) can receive a bonus of up to 10% from the pool
- All “qualifying APM participants” receive a bonus of 5% of total Medicare Part B payments in the prior year
- **Bonus is paid directly to the physician**, even if the Medicare Part B payments were made to another entity
- The bonus is paid “in a lump sum, on an annual basis, as soon as practicable”

Earning Bonus Requires Using EMR, Bearing Financial Risk, and Measuring Quality

**APM**
- CMS Innovation Center Programs
- Medicare Shared Savings Program (ACO)
- Health Care Quality Demonstration
- Patient Centered Medical Home

**Eligible APM**
- Uses certified EHR technology
- Pays for physician services using quality measures “comparable” to MIPS
- Bears financial risk “in excess of a nominal amount” OR is a CMS Innovation Center “medical home Phase II expansion model”

**Qualifying APM Participant**
- In 2019, receives at least 25% of Medicare payments through an APM
- Increases to 75% of payments by 2023 and includes both Medicare and private payers in determination
Medicare’s Accountable Care Organizations

- Many possible organizational and financing models:
  - Group practices of ACO professionals
  - Networks of individual practices of ACO professionals
  - Partnerships or joint venture arrangements between hospitals and ACO professionals
  - Hospitals employing ACO professionals

- Must serve at least 5,000 Medicare Fee-For-Service patients

- Shifting to 2-sided financial risk over time

APM Bonus Requires Minimum Share of Revenue

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<th>2019-20</th>
<th>2021-22</th>
<th>2023+</th>
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<tr>
<td>Medicare Revenue from APMs</td>
<td><img src="image" alt="25%" /></td>
<td><img src="image" alt="50%" /></td>
<td><img src="image" alt="75%" /></td>
</tr>
<tr>
<td>Medicare Revenue from APMs OR (Medicare + Other Payers) Revenue from APMs</td>
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Long-Term Advantage of APMs (2025 – 2045)

Annual Medicare Income

2025: $500K
2035: $513K / $539K
2045: $526K / $581K

PHYSICIANS’ DECISION-MAKING
Physicians Must Choose Whether To Participate in APMs, Report MIPS Measures, or Do Both

1. Qualifying APM?
2. MIPS Eligible?
3. Not Sure? Do Both?

Reporting Options Will Depend on Your Practice

Individual Practice  Partner in Group Practice  Hospital Employee

In 2015:
- Generally, ACOs report quality measures to CMS at the organizational level
- Individual ACO professionals have received PQRS bonuses based on the ACO’s reporting
- But if the ACO does not report quality measures, individual ACO professionals will receive PQRS penalties

In 2019:
- Reporting options will depend on whether you participate in an APM, and how much of your Medicare revenue comes from APMs vs. MIPS
CMS Decides Whether You’re a Qualifying APM Participant and Receive a Bonus Payment

1. Qualifying APM?

- CMS will determine whether you are “MIPS-eligible,” a “qualifying APM participant,” or a “partially qualifying APM participant”
- Physicians will not technically “choose,” especially if you have few eligible APMs because of your specialty or where you practice

RECEIVE 5% BONUS

What Happens If You Don’t Earn the APM Bonus? You’re Eligible for MIPS!

2. MIPS Eligible?

- No APM Bonus?
- Almost Met Threshold for Qualifying APM (Partially Qualifying APM Participant)
- Didn’t Come Close to Threshold
- “Hold Harmless” if You Did Not Report MIPS Measures
- No Relief from MIPS Penalty

MIPS Eligible?

- No APM Bonus?
What Happens If You Don’t Report MIPS Measures?

- A physician who almost meets the qualifying APM participant definition and does not report MIPS measures is a “partially qualifying APM participant” who does not receive either a 5% APM bonus or a MIPS downward adjustment.

- Any other physician is “MIPS-eligible” (thus will receive downward MIPS adjustment if he or she fails to report MIPS measures).

Estimated APM Bonus Pool for Interventional Radiology (2014)

Medicare Physician Fee Schedule Allowed Charges, 2014 = $273 million

5% bonus pool = $13.7 million

Sources: CMS, The Washington Post
Key Messages

- Largely business as usual through 2018 – threat of future SGR cuts is gone, but PQRS, VM and MU penalties phase in
- CMS will continue developing alternative payment models such as ACOs; success in the marketplace is not guaranteed and rules may evolve over time
- Specialty societies should drive development of quality measures, categories of resource use, and clinical practice improvement activities that describe their specialty
- Individual physicians and practices should identify opportunities to participate in alternative payment models to gain experience

Thank You!

Questions?

Paul Rudolf, MD, JD
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Jen Madsen, MPH
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Tab 3: Speaker Biographies
Paul M. Rudolf MD
Partner

Dr. Paul Rudolf has significant experience in both Medicare and FDA legal, regulatory and policy issues, particularly those relating to counterfeit drugs and radiofrequency identification technology as applied to pharmaceuticals and medical devices. He also is widely recognized for his experience with coverage, coding, and reimbursement issues for hospital and physician payment systems under the Medicare payment systems.

Dr. Rudolf practiced medicine for more than 15 years and taught at George Washington University before becoming a Medicare Carrier Medical director. He subsequently joined the Centers for Medicare and Medicaid Services where he led policy development for the physician fee schedule and the hospital outpatient prospective payment system, and became recognized for his in-depth experience with coding and reimbursement for Medicare. Dr. Rudolf left the Centers for Medicare and Medicaid Services to join the FDA where he was a senior advisor for medical and health policy in the Office of the Commissioner. At the FDA, he led policy development for counterfeit drugs and radiofrequency identification technology and worked on issues related to follow-on biologics and pediatric medical devices. After leaving government, Dr. Rudolf worked for Avalere Health LLC, where he consulted for a variety of clients including pharmaceutical manufacturers, medical device manufacturers, healthcare technology manufacturers and physician trade organizations.

Dr. Rudolf has served in a number of elected and appointed positions in organized medicine including service on the Board of Trustees of the Medical Society of the District of Columbia and as chairman of the young physician’s section of the American Medical Association. Dr. Rudolf has received numerous awards for leadership and performance from the Administrator of CMS and the Commissioner of the FDA.
Articles

- Paul M. Rudolf MD "New year, new code: Things to remember when billing for CCM" *Healio.com*, February 18, 2015
- Paul M. Rudolf MD "New year, new code: How to get paid for chronic care management in 2015, part 1" *Healio.com*, December 18, 2014
- Paul M. Rudolf MD and Abraham Gitterman "CMS proposes to share physician payment Sunshine Act data with federal agencies" *Healio.com*, June 10, 2014
- Thomas A. Gustafson PhD, Paul M. Rudolf MD and Nora Schneider "New law will modernize Medicare lab payments: What physicians need to know" *Healio.com* April 23, 2014
- Paul M. Rudolf MD "A Strategic Action Plan for Achieving Uncompromising 'Treat to Target' for Individuals with Insulin-Dependant Diabetes: A Report by the Center for Insulin-Dependent Diabetes Access' Blue Ribbon Panel" Diabetes Technology & Therapeutics 7:755-767, 2005
- Paul M. Rudolf MD "Counterfeit Drugs" NEJM 350:1384-1386, 2004
- Paul M. Rudolf MD "Employment Contracts" Today’s Internist, March-April 1999

Presentations

- Paul M. Rudolf MD and Nicole Liffrig Molife "What’s on the Horizon for CMS and Transparency in Health Care and Freestanding Centers" OEIS 2nd Annual National Scientific Meeting, Chicago, IL, April 11, 2015
- Paul M. Rudolf MD and Nicole Liffrig Molife "Chronic Care Management Coding for Care Coordination" Health Services Advisory Group, March 12, 2015
- Nicole Liffrig Molife and Paul M. Rudolf MD "Chronic Care Management Reimbursement Compliance: Overcoming Obstacles and Meeting Requirements" Healthcare Intelligence Network, February 12, 2015

Advisories

- "Saying Farewell to the Sustainable Growth Rate: Are Physicians Better Off Now?" Apr. 2015
- "CMS Rule Improves Business Case for ACOs but Challenges Remain" Oct. 2011

Paul M. Rudolf MD
Arnold & Porter LLP
- "Personalized Medicine: Reimbursement Changes Loom for Molecular Laboratory Tests" Mar. 2011
- "DC Circuit Invalidates Medicare "Least Costly Alternative" Policy" Jan. 2010
- "What's Coming in 2009 for Drugs, Devices, and Healthcare" Nov. 2008

**Government and Military Service**

- Medical Officer, US Centers for Medicare & Medicaid Services
- Senior Advisor for Medical and Health Policy, Office of the Commissioner, US Food and Drug Administration
Jennifer B. Madsen MPH  
Health Policy Advisor

Jen Madsen, MPH, advises clients across the healthcare industry on the development of policies to advance their strategic objectives.

Prior to joining Arnold & Porter LLP in 2015, Jen held leadership positions at the College of American Pathologists and the American Clinical Laboratory Association. At CAP, Jen led the team responsible for diagnostic laboratory and pathology CPT codes, Medicare coverage and payment, private health plan relationships, quality measurement, and accountable care. She led ACLA’s committee on FDA regulatory issues and advised on reimbursement concerns.

Jen has advocated extensively on behalf of molecular diagnostic laboratories and genomic sequencing tests, partnering with Personalized Medicine Coalition, American Medical Association, Association for Molecular Pathology, and American College of Medical Genetics. She has a broad network of relationships with decision-makers at CMS, Medicare contractors, the FDA, and private health plans, and knows how to get things done in Washington DC.

Previously Jen spent nearly a decade consulting and lobbying on health reform and Medicare policy issues. Her past clients include pharmaceutical and biotechnology companies, investors, patient advocates, trade associations, research foundations, healthcare providers, and the federal government. Early in her career she was a health economist with the nonpartisan Congressional Budget Office, a staff agency of the US Congress.

Professional and Community Activities

- Member, American Association of Medical Society Executives
- Member, Women in Government Relations

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Areas of Practice
FDA and Healthcare
Legislative and Public Policy

Education
MPH, Yale University, 1999
BA in Biochemistry, Rice University, 1997

Admissions
*Not admitted to the practice of law

arnoldporter.com
Articles

- Jennifer B. Madsen MPH "Supreme Court again holds key to future of Affordable Care Act: Preparing for the fallout" Healio.com, April 16, 2015


Advisories

- "Saying Farewell to the Sustainable Growth Rate: Are Physicians Better Off Now?" Apr. 2015
Tab 4: Practice Overview
FDA AND HEALTHCARE

For decades, Arnold & Porter LLP’s FDA and Healthcare practice has been a leader in helping pharmaceutical, biotechnology, medical device, and diagnostic companies, as well as other healthcare entities, respond to complex regulatory and compliance challenges in the US and Europe. We assist our clients in routine counseling matters, resolving their issues and concerns and supporting key business operations, as well as in the most complex crises—all with an eye on their long-term business and product goals. Our practice also has substantial experience in the regulatory issues faced by food, dietary supplement, and cosmetic product companies.

Unlike many firms that have separate FDA and healthcare practices, and even divisions within the FDA practice, Arnold & Porter believes that it is important for all of the lawyers and other professionals in our global FDA and Healthcare practice to understand all aspects of how biomedical products and services get to the marketplace, how governments and private entities pay for such products, how to develop and maintain compliant systems to avoid problems, and how to respond to investigations and enforcement proceedings. We instill this approach throughout our practice, including the cross-training of our associates.

Our teams in the US and Europe include experienced attorneys, many of whom have previous government agency experience—medical doctors, scientists, and public policy specialists. These professionals work together to provide our clients with seamless, comprehensive, and sophisticated analyses, and strong and zealous advocacy.

Audits and Investigations
We have deep experience in FDA and healthcare investigations and in avoiding and defending against enforcement actions, both in administrative proceedings and in court. We have negotiated landmark consent decrees or settlements with the FDA and the Department of Justice; represented companies on-site during extended hostile FDA inspections; managed high-profile congressional inquiries; represented clinical investigators in scientific misconduct and disqualification proceedings; and helped clients develop corrective action plans for various types of regulatory noncompliance. The combination of our regulatory experience with our healthcare and fraud and abuse experience can be critical in matters that straddle FDA and coverage and reimbursement, such as False Claims Act and Medicare/Medicaid Anti-Kickback Act matters involving alleged off-label promotion or misbranding.

We also regularly assist pharmaceutical, medical device, and biotechnology clients in evaluating the regulatory aspects of transactions, performing “due diligence” audits in many significant mergers and acquisitions, structuring the FDA and healthcare regulatory aspects of corporate and intellectual property transactions, and participating as regulatory counsel in public offerings of securities for pharmaceutical, medical device, biotechnology, and healthcare firms.

arnoldporter.com
Biosecurity
We have extensive experience with the various special statutory and regulatory frameworks applicable to products that contribute to biodefense and public health preparedness. In particular, we have advised a number of clients on strategies for seeking procurement decisions for national biosecurity stockpiles and associated policies and appropriations, and negotiated statutory and contractual protections for manufacturers of vaccines, antivirals, and other products to be used in response to a pandemic outbreak or bioterrorist attack.

Our attorneys also work with colleagues in the firm’s homeland security practice to assist clients in a broad range of industries as they work through the complex issues raised by the possibility of new and increased threats to personnel, facilities, and infrastructure, as well as the possible government need for critical goods and services during a time of emergency.

Coverage and Reimbursement
Our practice includes both lawyers and non-lawyer professionals who are leaders in counseling clients in developing and implementing strategies to achieve optimal coding, coverage, and reimbursement for healthcare products and services. We offer a special focus on counseling clients on Medicare coverage, including Part B and Part D coverage issues, as well as Medicaid, VA, and DOD matters. Our experience includes initiatives relating to the payment rules for all sites of care, product coding, coverage with evidence development, disease management, and CMS interactions with the FDA, AHRQ, NIH, and private payers.

We routinely assist clients in healthcare policy and legislative matters, tracking virtually every significant development that could have an impact on payment for our clients’ products and services, including developing federal and state laws related to drug pricing, coverage policies and procedures, and competitive bidding requirements.

We have also helped numerous clients comply with the privacy, security, and electronic transactions regulations implementing the Health Insurance Portability and Accountability Act (HIPAA). These clients include both HIPAA "covered entities" (e.g., health plans) and non-covered entities, including business associates of covered entities (e.g., information technology and service providers) and others that are affected by the regulations' restrictions.

FDA Strategy and Compliance
Our capabilities span the full range of US FDA matters, including developing regulatory strategies for novel products, advising on Hatch-Waxman Act and other FDA-related patent and exclusivity matters, achieving and maintaining compliance for marketed products, handling product recalls and other crises, responding to FDA enforcement actions, and advising on the regulatory aspects of product liability and False Claims Act litigation. We also have substantial experience in Drug Enforcement Administration issues and matters involving US state agencies and enforcement officials.

We regularly work with biomedical companies in determining how their products will be regulated, designing product development strategies to minimize review time, and presenting scientific and medical evidence to gain FDA approval or clearance. Similarly, we work effectively with clients on the increasingly complex issues relating to clinical trials. Our team has years of experience representing clients in shaping and challenging regulatory agency policies. We have
been successful in numerous petitions on behalf of clients asking the FDA to adopt rules protecting the rights of clients, to prevent unlawful approvals or other agency actions, or to reverse decisions adverse to clients’ interests. We have also successfully sued the FDA to reverse improper agency decisions.

Working closely with our patent and antitrust experts, we have extensive experience in life cycle management issues, including obtaining and maintaining exclusivities, successfully utilizing intellectual property protections, and preventing inappropriate approval of competitive products.

**Fraud and Abuse / False Claims**
In recent years, all participants in the biomedical and healthcare fields have been under intense federal and state scrutiny for possible fraud and abuse. Given current governmental budgetary and oversight pressures, the number of investigations and prosecutions for violations of fraud and abuse laws—including False Claims Act cases, at both the federal and state level—will only increase. Our experience in counseling companies on federal and state fraud and abuse laws extends back for more than two decades.

Our firm is well qualified to handle fraud and abuse investigations for pharmaceutical, medical device, and other healthcare clients due to our in-depth knowledge of these industries. Clients need lawyers who understand their businesses and who can think about preventive compliance, the changing policy environment, and enforcement litigation risk at the same time. An integral part of our fraud and abuse work involves developing offensive and defensive strategies relating to the Centers for Medicare and Medicaid Services (CMS), the Department of Veterans Affairs (VA), the Department of Health and Human Services, and the VA Offices of the Inspector General (OIG). Several of our partners have held high-ranking positions in these agencies.

We have extensive experience advising device, pharmaceutical, and biotechnology companies on the full range of issues arising under the Medicare/Medicaid Anti-Kickback Act, the False Claims Act, and other federal and state fraud and abuse laws. We regularly assist our clients in formulating compliance strategies, performing self-evaluative audits, designing compliance and corrective action plans, and mitigating liability—where appropriate—through self-reporting.

We have worked with numerous clients on forward-looking compliance assessments designed to (1) review broad categories of commercial activities, (2) examine whether existing compliance policies, procedures, and internal controls are sufficient, and (3) recommend steps to remedy identified weaknesses. We have also provided advice on compliance program development and implementation, and benchmarked programs against the OIG’s guidance, US Sentencing Commission guidelines, and peer company practices. Given the stakes, our overall approach is to help our clients detect and correct or prevent possible violations of law before they occur, and to help maintain successful interactions with the government.

We routinely work with our clients to respond to fraud and abuse initiatives, guidance, and litigation. We have lawyers experienced in both bringing fraud and abuse cases on behalf of the government and defending companies against the federal government and the states. We have been involved in some of the most high-profile civil and criminal fraud and abuse and false claims matters, and our litigators are well schooled in the latest theories of claimants and prosecutors.
We also help clients to structure commercial agreements to avoid violation of the Anti-Kickback Act and other fraud and abuse constraints. We often help structure agreements to comply with the safe harbors for discounts, personal services, and group purchasing organizations and have written policies for clients in connection with sales, marketing, and pricing strategies.

Healthcare and Pharmaceutical/Medical Devices Crises, Investigations and Enforcement

Corporations or individuals who face civil or criminal healthcare, pharmaceutical or medical device crises, investigations and enforcement turn to Arnold & Porter for our unparalleled depth of experience. With former agency counsel and more than a dozen former federal prosecutors who have experience dealing with healthcare specific issues for pharmaceutical and medical device manufacturers, hospitals, skilled nursing providers, physicians, as well as healthcare executives, we stand ready to focus on mitigating immediate risks. For some of the most complex and challenging issues across the life sciences and healthcare sectors, we have established a record of developing comprehensive and effective strategies to counsel and defend clients through all stages of internal investigations, recalls, inspections, audits, civil, criminal and congressional investigations, and trials.

Our team’s credentials consist of a former head of criminal healthcare fraud for the U.S. Department of Justice, former head of civil healthcare fraud enforcement for the Eastern District of Pennsylvania, two former heads of the Major Crimes Unit for the Southern District of New York, the former Assistant Solicitor General responsible for healthcare issues for the U.S. government, and an array of accomplished former Assistant United States Attorneys and FDA litigation counsel. Our litigators are complemented by a team of sophisticated regulatory attorneys who focus on FDA, HHS-OIG, and CMS matters. This collaboration delivers sophisticated and integrated legal counseling and a comprehensive commitment to achieving a successful outcome. Our focus remains addressing our client’s needs, always conscious that the ultimate goal is to avoid indictment, civil liability, exclusion, and adverse publicity.

We also routinely work with clients to develop proactive crises plans and procedures, and help them avoid future crises by conducting continuous improvement reviews to identify important gaps in controls relative to regulatory and compliance risks.

Pharmaceutical and Medical Device Industry Matters

- Represented leading pharmaceutical manufacturers in off-label promotion investigations and qui tams by the U.S. Department of Justice and U.S. Attorney’s offices in Massachusetts, Pennsylvania, Illinois, Tennessee, Florida, and New Jersey.
- Served as lead counsel in civil, criminal and congressional investigations into adulteration of heparin active pharmaceutical ingredient in the Chinese supply chain, which resulted in recalls of heparin-based products throughout the United States.
- Routinely assist clients in managing recalls of drug and medical device products, including numerous recalls involving products presenting significant human health risks and intense government and media scrutiny.
In the course of parallel criminal, civil, and administrative investigations involving a pharmaceutical product, we publicly filed First Amendment and statutory challenges to FDA's intended use regulations in federal court in Washington, D.C.

Represented a major diagnostic manufacturer in five simultaneous inspections at its manufacturing facilities in the U.S. and Europe.

Represented a medical device manufacturer in a major FDA enforcement challenge to the marketing of its new version of a product incorporating a wireless technology, ultimately resulting in the FDA dropping the enforcement challenge and issuing a guidance permitting continued marketing of the product.

Defended a manufacturer of diagnostic and medical imaging systems in an ongoing government investigation of the company's product discounts.

Conducted FCPA and Bribery Act internal investigations for a global biopharmaceutical company into issues surrounding the distribution of drugs and payments to physicians in several countries.

Defended a biopharmaceutical company in state and federal litigation and governmental investigations by the FBI, HHS-OIG, and multiple US Attorney's Offices, involving alleged promotional violations and Medicare and Medicaid fraud.

Represented senior pharmaceutical executives in FCPA investigations being conducted by the Fraud Section of the Criminal Division of the U.S. Department of Justice.

Conducted in-depth FCPA internal investigations for pharmaceutical and medical device manufacturers.

**Healthcare Industry Matters**

Represented a national healthcare consulting service in connection with the civil investigations of the company's emergency department operations in numerous *qui tam* centralized through multi-district litigation.

Represented numerous companies in a state Medicaid investigations led by state Attorneys General in over 25 states.

Represented physician practices in high-profile criminal and civil investigations, including *qui tam* litigation, in the Southern District of Florida, Central District of California, District of Maryland, and Eastern District of Virginia.

Filed statutory injunction challenging HHS Secretary's authority to suspend federal Medicare payments.

Counseled hospitals, large multi-specialty physician practices, smaller physician groups, individual physicians, multi-state physician practices, and medical societies and professional associations on federal anti-kickback and self-referral (Stark) laws, state fraud and abuse laws, and patient confidentiality.

Conducted internal audits and defend companies in investigations and litigation regarding allegations of fraud and abuse laws.
Hospitals
Arnold & Porter LLP’s healthcare attorneys for decades have represented hospitals, hospital systems, and other institutional healthcare providers, including some of the most established and nationally respected hospitals and healthcare systems in the country. We understand that operating a hospital is one of the most complex and regulated enterprises that one may undertake, whether on a for-profit or nonprofit basis. Our team of highly skilled attorneys includes a physician and a nurse practitioner who bring first-hand understanding of the industry. We work with hospitals and health systems on issues ranging from state matters such as licensure and certificate of need, to more global issues such as evolving healthcare delivery, reimbursement, and value-based purchasing models that can materially affect the financial success and even viability of the hospital services provider.

We are extremely familiar with the sensitivities arising from the need to maintain an active medical staff while competing with physician-owned ventures and complying with the Anti-Kickback, self-referral (Stark), and other fraud and abuse laws. Nonprofit tax-exempt hospitals face additional challenges arising out of the need to provide charity care and avoid private inurement issues, and management must report to boards or trustees that may include members who do not have an in-depth understanding of the hospital business. Hospitals must also contend with licensure, certificate of need, accreditation, and quality control issues, especially with the new Medicare hospital acquired condition provisions now in effect. Providing insights developed over years of industry experience and service in high-ranking positions at the Center for Medicare and Medicaid Services (CMS) and the US Food and Drug Administration (FDA), we understand the issues that hospitals and healthcare systems confront, and we have the experience, understanding of the law, and skills to help our hospital clients navigate their daily and long-term challenges.

Our group is complemented by a firm of over 700 litigation, regulatory, and corporate attorneys who work in related practice areas, including antitrust, real estate, mergers and acquisitions, tax, and criminal defense to provide clients with comprehensive service. At other times we are engaged to assist management or other counsel when a particular issue arises that requires the depth of our judgment, knowledge, and legal skills.

The following highlights some of the areas with respect to which we regularly provide advice and other legal services.

Accountable Care Organizations
Arnold & Porter LLP is distinguished as a national leader in providing physicians and health systems counseling and advice for developing Accountable Care Organizations (ACOs). Overcoming potential legal hurdles and business challenges when forming, structuring, and operating ACOs for participation in the Shared Savings Program under the Patient Protection and Affordable Care Act (PPACA) is critical to reducing unnecessary costs while improving quality of care. As new forms of integrated health systems continue to emerge, regulators are forging new pathways for reconciling the existing antitrust laws and referral laws, as well as other legal barriers to sustainability. Arnold & Porter attorneys are at the forefront of this rapidly developing area, and bring practical, innovative and results-driven strategies to physicians and hospitals. We are qualified to assist clients in ACO exploration, development, and operation as
we have the necessary experience in the substantive disciplines required for successful ACO
development and operation. By working together with our antitrust, regulatory, tax, corporate,
and transactional teams, our clients benefit from the full range of knowledge and experience we
offer.

Compliance and Fraud and Abuse

Arnold & Porter is a recognized leader in the field of healthcare compliance services. We have
designed, helped implement, and provided ongoing advice with respect to compliance programs
for hundreds of providers, including teaching and community hospitals, large regional hospital
and healthcare systems, professional practices, clinics, and a variety of similar entities. We have
performed in-depth and confidential compliance audits to help strengthen existing compliance
programs and ensure that they meet the "effectiveness" standard necessary to provide
protection for the hospital in case of an investigation or enforcement action. If and when the
issue arises, we assist our clients in assessing the need to make a voluntary disclosure where
potential problems have been identified, and if a decision to do so is made, we assist in the
development and presentation of such disclosures. In connection with the general compliance
plans, we also prepare Health Insurance Portability and Accountability Act (HIPAA) compliance
plans. We also regularly advise our clients regarding particular compliance matters relating to
issues arising out of charging, billing and coding, Anti-Kickback and Stark laws, national correct
coding initiative (NCCI) bundling, and patient confidentiality, among many others.

Reimbursement and Billing

We have significant experience in legal, regulatory, and policy issues relating to Medicare,
Medicaid, and private payers. We also have in-depth, up-to-date knowledge of hospitals,
physicians, and other providers under Medicare and other public and private insurance
programs.

Government Investigations and Enforcement

Our attorneys have successfully defended and advised some of the most substantial healthcare
providers in the nation with respect to investigations and proposed enforcement actions
pertaining to the False Claims Act, the Anti-Kickback law, the Stark law, and other federal and
state fraud and abuse laws by the Office of Inspector General (OIG), the Department of Justice
(DOJ), and state enforcement agencies. While we attempt to resolve these issues informally with
the applicable agencies, we are well experienced in defending our clients in court or through
administrative proceedings. In addition, our attorneys have negotiated and provided advice to
our healthcare clients relating to numerous Corporate Integrity Agreements.

White Collar Defense

Arnold & Porter's attorneys have a wealth of experience representing providers and suppliers in
criminal and civil enforcement proceedings. For those accused of cost report fraud, kickbacks,
money laundering, mail fraud, wire fraud, healthcare fraud, and questions of medical necessity,
our attorneys have successfully handled some of the most complex and challenging
investigations, cases, and trials in the country. We have the experience to effectively deal with
search warrants, grand jury subpoenas, civil investigative demands, administrative
demands/subpoenas, injunction actions, bond hearings, and trials. Our attorneys include former federal and state prosecutors from the US Department of Justice as well as US Attorney’s Offices around the country.

**Transactions**

Arnold & Porter's healthcare transactional attorneys combine drafting, negotiation, and strategic planning skills with an in-depth understanding of the legal and business constraints that are particular to the healthcare industry in general, and hospital/healthcare systems in particular. Accordingly, we have been able to close many substantial transactions on behalf of our healthcare industry clients, including mergers, acquisitions, dispositions, real property purchases, sales, leases, financing arrangements (including asset-backed loans, tax-exempt financings and mortgages), joint ventures with other healthcare providers, equipment and technology leases and licenses, institutional pharmacy contracts, vendor arrangements, and other sophisticated contracts. The firm’s multidisciplinary approach further ensures that we can cover virtually all aspects of a corporate healthcare transaction, including labor and employment, government approvals, regulatory compliance, real estate, and tax.

**Physician Contracting and Relations**

In addition to the more general transactional work referred to above, we have extensive experience with respect to matters involving physician contracts (including employment and under arrangement matters) and joint ventures with hospitals and other healthcare facilities. This includes, for example, federal and state Anti-Kickback restrictions on hospital contracts with physicians, anti-self-referral provisions, fee split, and other state fraud and abuse restrictions as they apply to compensation agreements, practice acquisitions and divestitures, and joint ventures involving hospitals and physicians.

**Managed Care Contracting**

Arnold & Porter has long been involved in issues relating to managed care in its many aspects. Our work includes managed care contracting, coverage and slow-pay disputes with commercial payers, and shared-risk agreements with hospital organizations.

**Clinical Research**

We have extensive experience in advising hospitals and academic medical centers on research-related regulatory requirements, drafting and reviewing agreements with research sponsors, clinical research organizations and investigators, and navigating issues associated with FDA and Institutional Review Board (IRB) clearance of research protocols. We have also assisted institutions in auditing their research operations for compliance with good clinical practice and related research issues. Arnold & Porter regularly represents institutions, IRBs, and individual clinical investigators in handling FDA inspections, investigations, and Warning Letters, scientific misconduct proceedings, research-related safety issues, Notices of Initiation of Disqualification Proceeding and Opportunity to Explain, and National Institutes of Health grant and Cooperative Research and Development Agreements matters.
Licensure and Certificate of Need

We frequently assist our healthcare clients in obtaining and maintaining state approvals, permits, and licenses, including Certificates of Need. This representation includes helping with preparation and submission of applications and related documents and forms, interfacing with the applicable governmental authorities charged with granting or denying such approvals, and appealing challenges to the grant or continuance of such approvals. In addition, approval issues often arise in connection with sales of healthcare industry businesses or other changes of control, including management arrangements.

Tax Exemption

Arnold & Porter's tax attorneys represent clients that qualify or attempt to qualify for federal and state tax-exempt status. These attorneys have an in-depth understanding of the issues relating to qualification for tax-exempt status, including debt-financed property, joint ventures with for-profit entities, executive compensation arrangements, corporate governance issues, tax-exempt bond financing, and other tax-exempt financing matters. As part of their practice, they often advise clients on private inurement issues. Moreover, they represent many foundations and intimately understand the grant-making process.

Antitrust

Arnold & Porter's antitrust practice is among the most prominent in the country and our antitrust attorneys advise our healthcare clients with respect to negotiating with third-party payors, exclusive provider arrangements, and developing specialty Preferred Provider Organizations. In addition, our attorneys have counseled healthcare providers in developing joint ventures, as well as in undertaking mergers and acquisitions.

mHealth and Emerging Technologies

Mobile Health and Health IT are revolutionizing the healthcare industry. From Electronic Health Records (EHRs) that coordinate patient care to mobile applications and Clinical Decision Support (CDS) tools that aid diagnosis, monitor symptoms, and track compliance with medications, healthcare technology is rapidly changing established healthcare delivery models and the rules that govern them. The new model for healthcare requires novel, yet practical approaches to address legal and regulatory issues and research, development, and marketing globalization of such emerging technologies. This model for healthcare delivery will impact cross-border regulations, policies, and best practices in many areas, including regulatory licensing and approval, quality and safety, coverage and reimbursement, market access, healthcare compliance, advertising and promotion, privacy and data security, and litigation and risk management. These issues affect everyone across the care continuum from patients, providers and payors, to developers and regulatory and compliance personnel. The mHealth and Emerging Technologies Group at Arnold & Porter combines diverse subject-matter experience, deep industry knowledge, international perspectives and innovative problem-solving to help our clients navigate the complex legal and regulatory issues in this thriving and constantly evolving industry.
Representative Matters

- Providing strategic advice to a global **telecommunications company** regarding the development, licensing, and marketing of integrated Health IT solutions, software, mHealth, and wireless products.

- Developed and executed training and compliance programs for business, legal, and regulatory personnel on complaint-handling, advertising and quality systems for mobile applications, and Medical Device Data Systems (MDDS).

- Advising **Fortune 100 Healthcare Company** on FDA regulatory requirements for mobile medical apps and Health IT, including premarket and post-market strategy and compliance, device classification issues, labeling, promotion and advertising, and licensing and vendor contracting issues.

- Providing cross-functional legal support to **Health IT company** regarding FDA regulatory matters, intellectual property issues, product licensing and transactional matters, privacy and data security protocols for software solutions, and development and implementation of standard operating procedures for promotional review, labeling, licensing, Sunshine Act compliance and management of physician relationships.

- Providing regulatory counseling and strategic advice to a **global pharmaceutical company** in connection with the launch of products that combine Health IT, mobile applications, and software tools to provide health management and disease prevention programs for consumers and healthcare providers.

- Advising **wireless medical device manufacturer and Health IT company** on Medicare reimbursement and coverage and fraud and abuse issues.

- Advising **remote monitoring, home sleep testing, and diagnostic imaging companies** on Medicare reimbursement and coverage matters, teleradiology and telehealth issues, state licensure requirements, and fraud and abuse issues.

- Providing healthcare regulatory and strategic advice to a **medical device company** exploring utilization of a telemedicine delivery model for its product.

- Conducted due diligence for **global pharmaceutical company** involving acquisition of physician and patient-directed healthcare media and multi-channel marketing platform, including Health IT solutions, mobile apps designed to assist healthcare professionals (HCPs) with management of daily workflow at the point-of-care when they make diagnostic, treatment, and prescribing decisions.

- Conducted due diligence review for **private equity company** involving asset purchase of medical device and Health IT solutions for patient diagnosis, electronic healthcare records and financial and operational systems for hospitals.

- Conducted due diligence for **global pharmaceutical company** on FDA regulatory issues, Medicare reimbursement and coverage, and fraud and abuse issues involving acquisition of a developer and supplier of remote cardiac monitoring services.
Physicians
Arnold & Porter LLP healthcare attorneys have extensive experience representing physicians, physician practices, hospital medical staffs, as well as healthcare-related ventures owned in whole or in part by physicians. Our physician clients include large multispecialty and single specialty physician practices, smaller physician groups, and individual physician practices. Additionally, we represent a number of medical societies and professional associations.

We understand the issues important to physicians based, in part, on our extensive experience representing hospitals, health systems, and other healthcare provider clients. Our healthcare practice includes a physician and a nurse practitioner; in addition, several members of our practice served as high ranking officials at the Center for Medicare and Medicaid Services (CMS), the U.S. Food and Drug Administration (FDA), and other federal and state agencies.

In short, we understand the challenges that physicians face in their practices and health-related investments and businesses, and we have the experience, understanding of the law, and skills to help them attain their goals and objectives. The following highlights some of the areas with respect to which we regularly provide advice and other legal services.

Compliance and Fraud and Abuse
Arnold & Porter is a recognized leader in the field of healthcare compliance services. We have designed, helped implement, and provided ongoing advice with respect to compliance programs for hundreds of providers, including teaching and community hospitals, large regional hospital and healthcare systems, professional practices, clinics, and a variety of similar entities. We have performed in-depth and confidential compliance audits to help strengthen existing compliance programs and ensure that they meet the “effectiveness” standard necessary to provide protection for the client in case of an investigation or enforcement action. If and when the issue arises, we assist our clients in assessing the need to make a voluntary disclosure where potential problems have been identified, and if a decision to do so is made, we assist in the development and presentation of such disclosures. In connection with the general compliance plans, we also prepare Health Insurance Portability and Accountability Act (HIPAA) compliance plans. We also regularly advise our clients regarding particular compliance matters relating to issues arising out of charging, billing and coding, Anti-Kickback and self-referral (Stark) laws, national correct coding initiative (NCCI) bundling, and patient confidentiality, among many others.

Reimbursement Appeals
We have significant experience in legal, regulatory, and policy issues relating to Medicare, Medicaid, and private payers. We have successfully represented physicians in hundreds of reimbursement appeals, including those arising from Recovery Audit Contractor and Zone Program Integrity Contractor audits, through the administrative law judge hearing process.

Government Investigations and Enforcement
Our attorneys have successfully defended and advised individual physicians as well as large physician practices with respect to investigations and proposed enforcement actions pertaining to the False Claims Act, the Anti-Kickback law, the Stark law, and other federal and state fraud and abuse laws by the Office of Inspector General (OIG), the Department of Justice (DOJ), and
state enforcement agencies. While we attempt to resolve these issues informally with the applicable agencies, we are experienced in defending our physician clients in court or through administrative proceedings. In addition, our attorneys have negotiated and provided advice to our clients relating to numerous Corporate Integrity Agreements and Individual Integrity Agreements.

**Practice Group Formation**

Arnold & Porter's healthcare attorneys have worked extensively with physicians in establishing, structuring, or restructuring physicians practice groups, both large and small. While our principal goal is assuring compliance with applicable laws and regulations, we also recognize the business realities of operating a medical practice and work with our clients to pursue both regulatory compliance and business success.

**Accountable Care Organizations**

Arnold & Porter LLP is distinguished as a national leader in providing physicians and health systems counseling and advice for developing Accountable Care Organizations (ACOs). Overcoming potential legal hurdles and business challenges when forming, structuring, and operating Accountable Care Organizations for participation in the Shared Savings Program under the Patient Protection and Affordable Care Act (PPACA) is critical to reducing unnecessary costs while improving quality of care. As new forms of integrated health systems continue to emerge, regulators are forging new pathways for reconciling the existing antitrust laws, referral laws, as well as other legal barriers to sustainability. Arnold & Porter LLP attorneys are at the forefront of this rapidly developing area, and bring practical and innovative results-driven strategies to physicians and hospitals. We are qualified to assist clients in ACO exploration, development, and operation as we have the necessary experience in the substantive disciplines required for successful ACO development and operation. By working together with our antitrust, regulatory, tax, corporate, and transactional teams, our clients benefit from the wide range of knowledge and experience we offer.

**Transactions**

Arnold & Porter's healthcare transactional attorneys combine drafting, negotiation, and strategic planning skills with an in-depth understanding of the legal and business challenges in the healthcare industry in general, and physicians and physician groups in particular. We have successfully completed transactions on behalf of physicians and physician groups, including mergers, acquisitions, dispositions, real property purchases, sales and leases, financing arrangements, joint ventures with other healthcare providers, equipment and technology leases and licenses, vendor arrangements, and other sophisticated contracts. The firm’s multidisciplinary approach ensures that we can cover virtually all aspects of a healthcare transaction, including labor, antitrust and employment, government approvals, regulatory compliance, real estate, and tax.

**Credentialing, Peer Review, and Professional Conduct Matters**

We represent our physician clients in connection with credentialing disputes, loss of privileges issues, and peer review matters with hospitals, insurers, and government agencies. In addition,
we have successfully assisted physicians in administrative and court licensure or professional misconduct proceedings.

Managed Care Contracting

Arnold & Porter attorneys have experience in a broad range of managed care matters. Our work includes managed care contracting, coverage, and slow-pay disputes with commercial payers, and shared-risk agreements with hospital organizations.

Government Approvals, Licenses and Certificates of Need

With respect to physician-related ventures that require state approvals, permits, and licenses, including Certificates of Need, we assist in the preparation and submission of applications and related documents and forms, interface with the applicable governmental authorities charged with granting or denying such approvals, and appeal challenges to the grant or continuance of such approvals.

Clinical Research

We have extensive experience in advising clinical investigators on their regulatory obligations, drafting and reviewing agreements with research sponsors and clinical research organizations, and navigating issues associated with FDA and Institutional Review Board clearance of research protocols. We also regularly represent investigators in responding to FDA inspections, investigations and warning letters, scientific misconduct proceedings, and Notices of Initiation of Disqualification Proceeding and Opportunity to Explain.

Antitrust

Arnold & Porter’s antitrust practice is among the most prominent in the country and our antitrust attorneys advise our healthcare clients with respect to negotiating with third-party payors, exclusive provider arrangements, and developing specialty IPAs, preferred provider organizations, and other forms of physician collaborative structures. In addition, our attorneys regularly provide counsel to physicians and physician practices in the development of joint ventures, as well as in undertaking mergers and acquisitions.

Commercial Litigation

Our litigators have represented physicians and other health care providers in commercial litigation matters including shareholder or vendor disputes, employment terminations, contract breaches and claims, and enforcement of restrictive covenants.

Pricing

Our team is experienced in providing a full range of counseling, litigation, and advocacy services on pharmaceutical pricing issues for our clients. We regularly provide advice, in-depth analyses, and internal training on calculating the various pricing metrics that are reported to federal agencies or that set price ceilings (e.g., AMP, Best Price, Section 340B, ASP, non-FAMP and federal ceiling price), and on related reporting and administrative requirements. We also
represent clients in negotiating Federal Supply Schedule (FSS) contracts and advise on the price disclosure and reporting requirements associated with FSS contracts.

We also represent companies in connection with litigation, internal investigations, and government audits concerning pharmaceutical pricing issues and have frequently assisted manufacturers in conducting reviews to evaluate the adequacy of existing compliance policies and procedures in the pricing area. Our representation of an industry trade association on pricing and related legislative matters, combined with our work for a diverse range of individual companies, has given us a distinct, industry-wide perspective of the pharmaceutical pricing landscape.

Major manufacturers and a leading industry trade association rely on us for advice on the intersection of state and federal fraud and abuse laws with developing government pricing and reimbursement issues. Our activities in this area include analyzing state and federal regulations, developing offensive and defensive pricing, coverage and reimbursement strategies, and government advocacy.

**Policy**
We regularly track and advise on virtually every significant pharmaceutical-, biotechnology-, and medical device-related legislation considered on Capitol Hill and state legislatures. Our distinct combination of regulatory and public policy experience provides clients with the most effective advocacy in both offensive and defensive legislative matters. We are leaders in helping our clients anticipate and shape new statutory and regulatory challenges, from drug and device safety legislation to drug importation to the development of a follow-on biologics framework.

**Risk Management**
In addition to routine counseling on a wide variety of compliance matters, ranging from review of promotional materials to adverse event reporting and manufacturing questions, we routinely assist clients in performing self-evaluative audits, designing corrective action plans, and reporting possible violations to regulatory authorities. In recent years, we have undertaken reviews of regulatory compliance operations for various types of FDA-regulated companies, including prescription drug manufacturers, biotechnology companies, medical device manufacturers, and a major blood-banking organization; engaged in comprehensive investigations of sales and promotional practices to assess conformity to corporate and legal standards; and conducted audits of manufacturing records and pharmacovigilance systems to determine adherence to FDA requirements. We work closely with our colleagues in various areas—including the Foreign Corrupt Practices Act, criminal defense, antitrust, and product liability matters—to maximize the risk management impact of such compliance efforts.

**European Practice**
Working with colleagues in the US or separately on discrete EU matters, the members of our London team provide complementary advice on all aspects of EU regulatory law and procedures for companies in the pharmaceuticals (human and veterinary), biotechnology, homeopathic, herbal, and medical device sectors.

We have significant experience in advising the suppliers of both prescription-only and over-the-counter products and have developed special experience in the field of novel technology.
products such as gene-based, cell-based, and tissue-engineered products. We also have substantial experience in relation to borderline products and mainstream cosmetic, food supplement, and biocide products.

We provide contentious and non-contentious advice side-by-side and have represented clients in many administrative law proceedings against regulatory agencies before both UK national courts and the European Court of Justice.

Our London team includes a significant number of lawyers who are also qualified in medicine, toxicology, pharmacy, or other scientific disciplines and has strong links with local and community trade associations, regulators, and members of the scientific community. The group also has a network of preferred specialists in other jurisdictions within and outside the EU with whom it collaborates when matters raise both local law issues as well as overarching aspects of EU law.

**Regulatory.** In the pharmaceutical and biotech field, we provide advice on the full gamut of regulatory matters from pre-clinical/GLP, through clinical research/GCP and compassionate use/named-patient supply issues, to manufacturing/GMP and wholesale dealing/GDP questions. We advise on all types of post-marketing obligations, including advertising, patient information, classification of medicines, pharmacovigilance, data privacy, and product lifecycle management. We have substantial experience in defending companies in the context of enforcement actions taken by either self-regulatory bodies or the competent national authorities.

We have helped clients in relation to every aspect of the process required to gain marketing authorizations in Member States (whether through the national, decentralized or mutual recognition procedures) or from the EMEA/European Commission through the centralized approval route. We have extensive experience in relation to the particular issues raised by orphan drugs, pediatric research, conditional authorizations, and authorizations based upon “exceptional circumstances,” and have steered many clients through appeal procedures at the national and community level.

We have acted for many innovator companies on issues concerning generics or biosimilars and have represented clients in a high proportion of the proceedings concerning regulatory data protection rights that have arisen both at the national level and in the many references to the European Court that have resulted from such national proceedings.

We provide counsel regarding the regulatory regime for medical devices, including active implantables and in vitro diagnostics. This includes issues relating to CE marking, vigilance, and recall. We have considerable experience in classification issues on the borderline between medicinal products and medical devices and in relation to drug/device or biological/device combinations.

**Pricing and Reimbursement.** We advise clients on pricing and reimbursement issues and have a very substantial practice advising clients on technology assessments, whether conducted by the National Institute for Health and Clinical Excellence, the Scottish Medicines Consortium, or the All Wales Medicines Strategy Group. We have represented many clients successfully in appeals against provisional determinations.
**Product Liability.** We have significant experience advising on non-contentious and contentious product liability relevant to the pharmaceutical, medical device, and related medical product sectors. We have conducted the defense of claims relating to marketed products and products still under research. We have represented clients in a high percentage of the major multiclaimant group actions that have been pursued in the United Kingdom in the last 25 years and have coordinated product liability proceedings across the EU. Many of these proceedings have involved jurisdictional questions, particularly forum shopping by claimants between the EU and US. We have also worked on two of the largest worldwide schemes of compensation established through US court procedures.

**Other Matters.** Working with specialists within the firm on patents, trademarks and copyright, or in competition law, our European regulatory lawyers assist in providing thorough and timely advice on issues that require a cross-section of skill sets, such as on the rules governing parallel imports, parallel distribution, or counterfeits, and in the drafting of clinical trial, distribution, co-marketing, co-promotion, or other collaborative agreements. We frequently advise upon the regulatory aspects of due diligence in corporate and commercial transactions.

**US Healthcare Reform**

On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act (PPACA), the comprehensive healthcare reform bill, and one week later he signed the Health Care and Education Reconciliation Act of 2010, which supplements and “fixes” several provisions of PPACA. Together, these laws will profoundly affect every stakeholder in the US healthcare system. In particular, pharmaceutical and medical device manufacturers, insurers, pharmacy benefits managers (PBMs), and healthcare providers will find that the implementation of these laws will bring significant challenges.

Arnold & Porter LLP has been working with clients to understand these new laws and to prepare for their forthcoming implementation. Our lawyers and other professionals have extensive experience in many of the areas affected by the comprehensive reform. These include: Medicare reimbursement, Medicaid rebates, section 340B drug discounts, biosimilars, healthcare fraud, waste, and abuse laws, legal and policy issues posed by comparative effectiveness research, and manufacturer obligations to report payments to healthcare professionals.

Now that PPACA and the Reconciliation Act have been signed into law, the US Department of Health and Human Services, the Centers for Medicare and Medicaid Services, the Health Resources and Services Administration, the US Food and Drug Administration, and other agencies will be issuing regulations and guidance implementing a number of provisions of the health reform laws. We will update this chart as implementation commences, adding key documents from these government agencies. We have also incorporated relevant documents on recent related laws and bills that include important healthcare reforms.

With many years of experience in virtually every area of healthcare law and legislation, Arnold & Porter’s multidisciplinary team offers sophisticated analysis, strategy, and advocacy in meeting the challenges of these wide-ranging reforms and helping our clients adapt to the dramatically changing landscape of healthcare.
Tab 5: Supporting Material
Saying Farewell to the Sustainable Growth Rate:
Are Physicians Better Off Now?
Paul M. Rudolf, MD, Rosemary Maxwell, Jennifer B. Madsen*, MPH, and Lauren L. Haertlein
April 2015

On April 14, the Senate passed H.R. 2, the “Medicare Access and CHIP Reauthorization Act of 2015,” which had passed the House on March 26 and is now on its way to the President’s desk. HR 2 permanently repeals the long-maligned Sustainable Growth Rate (SGR) payment formula that has helped govern how Medicare pays physicians.

This new law replaces the SGR with a small, stable payment update, builds on current pay-for-performance programs, and accelerates adoption of alternative payment models (APMs). These changes will cost the federal government and taxpayers $175 billion over the next decade, according to the Congressional Budget Office.\(^1\) On the surface, it seems obvious that physicians and other stakeholders in the healthcare industry will be better off. But a careful analysis shows that physicians’ economic incentives will be vastly different in the future, with important implications for makers of medical technology. Physicians are gatekeepers to medical technology -- they prescribe drugs, order laboratory and imaging tests, and recommend surgical procedures. Over time, the changes in Medicare’s payment system could cause physicians to prescribe different or fewer drugs or order fewer laboratory and imaging tests.

The most recent government estimates of future healthcare spending are at a historic low after years of increases.\(^2\) Policymakers have used a variety of methods to address concerns about over-use of medical technologies, including the “misvalued codes” initiative, increased public transparency of Medicare’s payments to physicians for specific services, and the implementation of the Sunshine Act. Other recent

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*Not admitted to the practice of law

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\(^1\) This figure is CBO’s estimate of Title I of the new law, “SGR Repeal and Medicare Provider Payment Modernization.” It is dated March 25, 2015, as H.R. 2 was under consideration by the House, and is available at [https://www.cbo.gov/sites/default/files/cbofiles/attachments/hr2.pdf](https://www.cbo.gov/sites/default/files/cbofiles/attachments/hr2.pdf).

policy changes, including the implementation of appropriateness criteria for imaging services, and a shift of payment for laboratory services to a market-based system, will also put downward pressure on Medicare’s spending for many of the services that physicians order.

This Advisory describes why the SGR was created, how Medicare’s procedures of paying physicians will change in the future, and how those changes will affect physicians’ incentives to use medical technology.

**History of SGR Overrides**

The SGR story is one of the tensions between reigning in healthcare costs and how to apply the fiscal prudence necessary to do so. In theory, the SGR was a fiscally responsible policy designed to allow Medicare’s payments to physicians to increase over time but not to rise too fast. Established in the Balanced Budget Act of 1997, the formula allows for growth in payments year-over-year by including factors for increases in the prices of inputs, such as medical equipment and supplies, and growth in Medicare’s enrollment. The formula also factors in growth in the volume of services, based on growth in per-capita gross domestic product (GDP).

The rationale for setting GDP as the target is that if the economy grows, then payments can increase. But if the economy contracts -- as in the financial markets’ crash in the early 2000s -- the SGR formula produces negative payment updates. Since then, the volume and intensity of physician services have grown much faster than the overall economy, widening the funding gap each year. Compensating for the payment cuts became an annual (or more frequent) exercise for Congress.

By accepting the argument of physicians that it was unfair to penalize them for a sputtering economy when other healthcare providers were not similarly affected, policymakers rejected the fiscal restraint that the SGR was designed to maintain.

**Long-Term Economic Outlook**

From 2000 to 2012, Medicare’s payment rate for physician services increased by a total of nine percent. But spending per beneficiary increased by 72 percent over that period, and certain physician services
accounted for most of the increase in spending. The volume of tests grew by 90 percent, and the volume of imaging grew by 73 percent. By comparison, the volume of physician office visits grew by 34 percent.\(^3\)

The chart below displays total healthcare spending in the US as a percent of GDP. In 1965, the year Medicare began, healthcare spending was 5 percent of the economy. By 1985, it had doubled -- to 10 percent of the GDP -- and stands just under 18 percent in 2015. In comparison, healthcare spending (as a share of GDP) in other developed countries ranges from a low of about 9% in the United Kingdom, Iceland, and Norway to about 12% in Austria, France, and the Netherlands.\(^4\)

The Centers for Medicare and Medicaid Services (CMS) currently projects that as a share of GDP, healthcare spending will remain just under 18% for the next five years, and grow to 19.3% by 2023. The Medicare Payment Advisory Commission (MedPAC) notes that in the future, “the pharmaceutical pipeline is shifting toward greater numbers of biologic products and specialty drugs, many of which have few therapeutic substitutes and high prices. This will put additional upward pressure on program spending….\(^5\)

\(^4\) World Bank.
\(^5\) Ibid.
Alternative Payment Models

The Department of Health and Human Services (HHS) recently set a goal of tying 30% of fee-for-service (FFS) Medicare payments to quality or value through APMs by the end of 2016, growing to 50% by 2018. The APMs could include, for example, bundled payment initiatives or accountable care organizations (ACOs). These projections may be optimistic; the Brookings Institution has noted that becoming an ACO is “often cumbersome and uncertain” and that “[t]here is not a “one size fits all” model for an ACO; organizations have both different starting points and different opportunities to transform care based on their current capabilities.”6 Further, the impact on spending of achieving of this goal is unclear, based on recently announced results from the Medicare Shared Savings Program, in which most ACOs improved quality, but did not reduce costs.7

Even if ACOs do not proliferate, other changes to Medicare’s payment system for physicians will affect physicians’ behavior. Physicians who do not perform well on Medicare’s quality and efficiency measures will see payment rates reduced, and those penalties grow larger over time. Thus, physicians will want to identify ways to increase efficiency and reduce their risk by, for example, consolidating into larger group practices that have invested in electronic health records (EHRs) and have the capability of reporting quality measures at the practice group level rather than at the individual physician level.

New Physician Payment System: Stability and New Incentives

From July 2015 to 2018, Medicare’s base payment rate will increase by 0.5% each year — a small, predictable update. Starting in 2019, Title I of H.R. 2 establishes a two-track system for Medicare’s payments to physicians.

In the first, physicians must meet goals for providing high-quality and low-cost care in order to obtain 100% of Medicare’s annual update to payment rates. Over time, Medicare’s payment penalties increase, incentivizing lower-performing physicians to improve. The Act creates the Merit-Based Incentive Payment System (MIPS), which combines the current pay-for-performance programs into a single payment system.8 It combines and builds on the infrastructure of three prior incentive programs, the Physician Quality Reporting System (PQRS), the Value Modifier (VM), and Meaningful Use (MU) programs. These

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7 http://www.brookings.edu/blogs/up-front/posts/2014/10/09-pioneer-aco-results-mcclellan#recent_rr/.
8 New Social Security Act (SSA) § 1848(q).
programs will sunset at the end of 2018. The Act also attempts to address some physicians’ concerns about appropriate measurement, attribution, and administrative burden.

The second track provides an alternative route to higher payments starting in 2019 and ending with 2024. It provides physicians and other eligible professionals a 5% annual bonus if they met the standards for “qualifying” participants in APMs, which require that a significant share of a physician’s revenues comes from an APM that takes on risk of financial losses, follows a quality measurement program, and uses certified EHR. Eligible professionals are not considered to be “MIPS-eligible professionals” if they are in a “qualifying APM” or a “partially qualifying APM.”

For 2026 and future years, there will be different annual updates to the conversion factor used in setting payment rates under the Medicare physician fee schedule. For providers paid through qualifying APMs, payment rates will be increased each year by 0.75%. Payment rates for other providers will be increased each year by 0.25%.

The tables below compare the new payment parameters with those that would have existed under prior law. The second line of the table shows the annual updates to the conversion factor will be under H.R. 2, but performance of individual physicians under the incentive programs can result in their payments being increased or decreased from that base (and failure to report under PQRS can decrease payments).

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9 Generally these provisions apply to “eligible professionals” (a somewhat broader group than physicians) but for brevity this summary often refers to “physicians” as a shorthand. Initially, MIPS will apply to doctors of medicine; osteopathy; dental surgery or medicine; pediatric medicine; optometry; chiropractors; physicians assistants; nurse practitioners; clinical nurse specialists; and certified registered nurse anesthetists.
First Decade Following Enactment of H.R.2 (Rest of 2015 to 2025)

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<td>-4.5%</td>
<td>-6.0%</td>
<td>-9.0%</td>
<td>-10% or More</td>
<td>-11% or More</td>
<td>-11% or More</td>
<td>-11% or More</td>
<td>-11% or More</td>
</tr>
<tr>
<td>MIPS Penalties</td>
<td>-4.5% (Same as prior law)</td>
<td>-6.0% (Same as prior law)</td>
<td>-9.0% (Same as prior law)</td>
<td>-10% or More (Same as prior law)</td>
<td>-4% (extra bonus possible)</td>
<td>-5% (extra bonus possible)</td>
<td>-7% (extra bonus possible)</td>
<td>-9% (extra bonus in 2022-2024)</td>
</tr>
</tbody>
</table>

Second Decade Following Enactment of H.R.2 (2026 And Future Years)

<table>
<thead>
<tr>
<th>Updates to Conversion Factor</th>
<th>MIPS Participants</th>
<th>0.25%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pay-for-Performance Bonus / Penalty Adjustment</td>
<td>Qualifying APM Participants</td>
<td>0.75%</td>
</tr>
<tr>
<td>May continue after 2024</td>
<td>No additional bonus payments available after 2024</td>
<td></td>
</tr>
</tbody>
</table>

As shown in the tables, policymakers are relying on bonus payments (and different conversion factors starting in 2026) to incentivize participation in APMs.
The extent to which these efforts will succeed in slowing future growth of Medicare spending depends on a variety of factors, including the trade-offs facing physicians as healthcare delivery models continue to change. The Physician Fee Schedule reforms do not change the underlying basis for valuing physician services. While the AMA-RVU Update Committee (RUC) has been criticized in recent years, its role in determining the relative values of physician services is unchanged by H.R. 2.10

Further, payments to professionals paid under the PFS include payments for certain medical technologies that are provided in physician offices, including physician-administered drugs, imaging, pathology services, and laboratory tests, etc. (Drugs are not paid under the PFS but at 106% of Average Sales Price. Their payments will not change under MIPs but could change under APMs.) At the margin, Medicare’s payments for medical technologies may be higher than they would under other payment systems, to the extent that payments are influenced by behaviors such as increasing the volume of tests ordered or choosing higher-cost drugs rather than lower-cost alternatives. Over time, the Act may mitigate such incentives, but it does not eliminate the linkage between use of medical technology and physicians’ incomes.

Quality Measurement in the MIPS

The PQRS program is designed to pay physicians more if they satisfy certain quality reporting requirements. Those incentive payments started at 1.5% in 2007 and 2008, rose to 2.0% in 2009 and 2010, and have declined since then to 1.0% in 2011, and 0.5% in 2012, 2013, and 2014. No PQRS bonuses are available in 2015 or future years.

Starting in 2015, the PQRS program is phasing in penalties for physicians who fail to report on the quality measures. Large multispecialty group practices that did not participate in PQRS in 2013 are receiving a 1.5% payment cut in 2015. The penalties will apply to smaller groups and to individual physicians in future years.

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Bonus and penalty payments are significantly lagged. In 2015, physicians are receiving payment penalties based upon their reporting in 2013. H.R. 2 includes provisions to shorten this lag and give physicians more immediate feedback on their performance.

Under H.R. 2, every year, the Secretary will publish a list of quality measures used to assess providers in MIPS. Measures must be “evidence based.” Before a new quality measure is added to an annual final list, “the Secretary shall submit for publication in applicable specialty-appropriate peer reviewed journals such measure and the method for developing and selecting such measure,” consult relevant professional organizations and other stakeholders, and go through rulemaking.

Quality measures used by a qualified clinical data registry are not subject to the notice-and-comment, peer review, or evidence-based focus requirements but are subject to a requirement to seek input from stakeholders. Existing quality measures also are not subject to the notice-and-comment or peer review requirements and are presumptively included among the quality measures.

The Secretary, with stakeholder input, must develop and publish a plan for the development of quality measures for use in the MIPS and in APMs, and post a draft plan on the CMS website by January 1, 2016. The plan will describe how measures from the private sector and integrated delivery systems could be used in Medicare and “how clinical best practices and clinical practice guidelines should be used” in developing quality measures.

In developing the draft plan, the Secretary must prioritize: (1) outcome measures; (2) patient experience measures; (3) care coordination measures; and (4) “measures of appropriate use of services, including measures of over use.” Starting May 1, 2017, and annually thereafter, the Secretary must report on the progress made in developing quality measures, including descriptions of the measures in development, a timeline for their completion, and plans for future quality measures. CMS can use up to $15 million per year in 2015 to 2019 to fund measure development.

**Resource Use Measurement in the MIPS**

The VM is designed to give physicians incentives to provide high quality and efficient care. The method for calculating the VM examines the quality and cost of services provided during an “episode of care,” a

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11 Under 42 U.S.C. § 1395w–4(k) and (m).
defined set of services provided to a patient with specific healthcare conditions over a period of time. Under prior law, CMS was required to penalize physicians in 2017 based on the quality and cost of services they provide in 2015.

Physicians have repeatedly expressed concerns that the episodes of care must be appropriately structured to account for differences in the acuity of patients served, so that physicians are not penalized simply because a patient they treated was sicker than another patient. Concern about risk adjustment is not new and has been a subject of ongoing debate between CMS and providers paid under all of Medicare’s prospective payment systems -- hospitals, nursing homes, home health agencies, etc.

The Secretary is required to post a draft list of care episodes and obtain public comment, but is not required to use notice-and-comment rulemaking. Within 180 days of enactment, HHS must post on the CMS website a list of episode groups. During a comment period, stakeholders can propose additional episode groups, as well as specific clinical criteria and patient characteristics to classify patients into “care episode groups” and “patient condition groups.” The Secretary must establish care episode groups and patient condition groups that are designed to account for 50% or more of Part A and B expenditures, and assign codes to the groups. Within 270 days of the end of the comment period, the Secretary must post an “operational list” of the care episode and patient condition codes on the CMS website. The codes will be updated annually in the Physician Fee Schedule regulations.

In measuring resource use, the Secretary “shall use per patient total allowed charges for all services under Part A and [Part B] (and, if the Secretary determines appropriate, Part D) . . . by care episode codes and by patient condition codes.” The Act precludes administrative or judicial review of the care episode and patient condition groups and codes, patient relationship categories and codes, and measurement of resource use.

Meaningful Use and the MIPS

The Meaningful Use (MU) program is designed to give eligible physicians (EPs), hospitals, and critical access hospitals (CAH) incentives to adopt and meaningfully use certified electronic health records technology (CEHRT). Under prior law, CMS was authorized to provide incentive payments to providers that are meaningful users and also mandated payment reductions for providers that are not meaningful users under the Medicare program starting on January 1, 2015 for EPs.
Today, providers are complying with different stages of meaningful use. Each stage (Stage 1 and Stage 2) has its own set of requirements that must be met in order to demonstrate meaningful use. The requirements become more rigorous as EPs and eligible hospitals proceed through the stages. In March 2015, CMS published its Stage 3 Proposed Rule. The Stage 3 Proposed Rule proposes that all providers will use the same set of Stage 3 meaningful use requirements starting in 2018, regardless of the previous stages of participation, and report those requirements for the entire calendar year under the Medicare program.

The Stage 3 Proposed Rule proposes a single set of eight objectives and associated measures in the following areas: (1) protect patient health information; (2) electronic prescribing (eRx); (3) clinical decision support (CDS); (4) computerized provider order entry (CPOE); (5) patient electronic access to health information; (6) coordination of care through patient engagement; (7) health information exchange (HIE); and (8) public health and clinical data registry reporting. All of the measures for the first five objectives are required. For Objectives 6 and 7, providers are required to attest to (1) using all three measures and (2) successfully meeting two out of the three measures. For Objective 8, EPs must attest to three of the measures numbered one through five. Eligible hospitals and CAHs must attest to four out of the six measures.

H.R.2 sunsets the current MU program and makes use of CEHRT one factor in the combined value-based incentive system with significant payment adjustments in 2019, as discussed in more detail below. Furthermore, H.R.2 will require providers attesting under the MU program to demonstrate that they have not “knowingly and willfully taken action . . . to limit or restrict the compatibility or interoperability of the certified EHR technology.” This new requirement will be effective within one year of enactment.

H.R.2 declares it a national objective to achieve widespread interoperability between meaningful EHR users and other clinicians and healthcare providers. No later than July 1, 2016, the Secretary is required to meet with stakeholders to develop measures to determine interoperability. If the Secretary determines that the goal has not been met, she is required to report to Congress no later than December 31, 2019. The Secretary’s report must identify barriers to such objective and make recommendations to achieve that objective. Such recommendations may include payment adjustments for not being meaningful users under the Medicare program and criteria for decertifying CEHRT products.
New Category: Clinical Practice Improvement Activities

The new law creates a fourth category for assessing physician performance, called clinical practice improvement activities (CPIAs). A CPIA is defined as an “activity that relevant eligible professional organizations and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes.” The Secretary must solicit recommendations from stakeholders to identify such activities.

Certain activities automatically increase a physician’s CPIA score. Physicians in patient-centered medical homes or comparable specialty practices receive the highest CPIA scores. Those in APMs receive a minimum score of 50% of that amount. Therefore physicians have some incentive to participate in APMs even if their participation level is not high enough to make them “qualifying APM participants” (a category discussed below that receives 5% APM bonuses rather than MIPS incentives).

Combining the PQRS, VM, MU, and CPIA Into a Composite Score

H.R. 2 eliminates the penalties that would otherwise apply in the PQRS, VM, and MU programs. Instead, physicians’ individual performance on quality, cost, and MU will be used, along with the CPIAs, to determine a single composite score ranging from 0 to 100. The categories are weighted, combining quality (30%), resource use (30%), clinical practice improvement activities (15%), and EHR meaningful use (25%).

Each physician’s composite score will be compared to a performance threshold that consists of the mean or median of the composite performance scores for all participants during a prior period of time. All physicians who achieve a composite score above the performance threshold are eligible for positive incentive payments.

The higher a physician’s composite score, the higher the “rate adjustment factor.” The rate adjustment factor is up to 4% in 2019, 5% in 2020, 7% in 2021, and 9% in 2022 and thereafter. This means that in 2019, a physician who receives a composite performance score of 100 gets a 4% adjustment, and a physician who receives a score of 0 gets a -4% adjustment. Subject to the availability of funds, the

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12 The weights can be adjusted in the first two years and of the MIPS, and the weight for MU can be reduced (from 25% to 15%) if the Secretary determines that 75% of eligible professionals are meaningful EHR users.
Secretary may reward exceptional performance. The aggregate additional incentive payments will be capped at $500 million for each year from 2019 through 2024.

Scores for outcome measures that are used in the resource use or quality performance categories are to be risk-adjusted, taking into account several HHS studies that will assess appropriate adjustments to quality measures, resource use measures, and other measures, and apply those adjustments to the performance scores and payments in the MIPS.

Scores for quality and resource use must (if sufficient data is available) take into account a physician’s improvement over time after the first year of the MIPS. Scores for clinical practice improvement activities and meaningful use of certified EHR technology may take such improvement into consideration.

The Secretary must make available physicians’ MIPS composite performance scores and their performance in each category of MIPS on CMS’ “Physician Compare” Internet website and must, if feasible, include on the website the names of physicians in eligible APMs.

Beginning July 1, 2017, the Secretary must provide confidential, timely feedback to physicians on their performance under the quality and resource use categories and may make available confidential feedback regarding the other performance categories. Beginning July 1, 2018, the Secretary must make information available to MIPS-eligible professionals about items and services furnished to the patients they treat by other suppliers and providers.

Technical assistance will be available to help smaller practices (15 or fewer professionals) improve MIPS performance or transition to APMs, with priority given to rural and underserved areas. $20 million is provided for implementation from 2016 to 2020.

Incentives for Physicians to Join Alternative Payment Models

The Act adds a new SSA § 1833(z), “Incentive Payments for Participation in Eligible Alternative Payment Models.” An APM includes: “a model” under SSA § 1115A (establishing CMMI, the Center for Medicare and Medicaid Innovation within CMS), except a health care innovation award; the Medicare Shared Savings Program (MSSP); a demonstration project under SSA § 1866C (“Health Care Quality

This appears to include a CMMI Phase I “testing” model or a Phase II “expansion” model.
Demonstration Program”); or a demonstration “required by federal law” (potentially this could include gainsharing demonstrations).  

Bonus payments to “qualifying APM participants” (discussed below) are actually tied to the degree to which they furnish services through an “eligible APM.” An “eligible APM” is an APM that: (1) uses certified EHR technology; (2) pays for covered professional services based on quality measures “comparable to” those used under the MIPS; and (3) is either a model in which “one or more entities bear financial risk for monetary losses that are in excess of a nominal amount” or is a CMMI medical home Phase II “expansion model.”

Starting in 2019 and “ending with 2024,” physicians and other eligible professionals who are “qualifying APM participants” receive a bonus “equal to 5 percent of the estimated aggregate payment amounts for . . . covered professional services” under [Medicare Part B] for the preceding year.” The base for determining the bonus is the **total payment for all professional services furnished under Part B**, whether furnished under an APM or under the MIPS regime.

The 5% bonus for qualifying APM participants runs from 2019-2024; it appears there is no preferential payment for qualifying APM participants in 2025; and then beginning in 2026, there is a preferential “qualifying APM conversion factor” (1% vs 0.5% for the “non qualifying APM conversion factor”). Qualifying eligible APM participants are not MIPS participants, and thus could not receive MIPS incentive payments as well as a 5% APM-participation bonus.

A “qualifying APM participant” derives at least a threshold percentage of his or her annual professional services payments from services furnished under eligible APMs or APM-like models. (These percentage payment threshold requirements pertain to payments over “the most recent period,” which may be less than a year.) Starting in 2019, at least 25% of the physician’s payments for Medicare Part B services

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14 Note that under these authorities, CMS could include Part D drugs or drug costs in APMs (for example, CMMI’s authority to test and expand models extends to Part D).

15 The requirement that one or more entities “bear financial risk for monetary losses … in excess of a nominal amount” is not entirely clear; it could mean that one or more entities must bear a non-trivial level of financial risk, or that they must bear financial risk for any losses exceeding a stated loss amount considered nominal.

16 “Covered professional services” has the meaning given in SSA § 1848(k)(3)(A) (p. 97), i.e., “services for which payment is made under, or is based on, the fee schedule established under this section and which are furnished by an eligible professional.”

17 The Act also includes an alternative standard to be a “qualifying APM participant” that is based on volume of patients rather than payments.
must come from services attributable to eligible APM participation. The threshold percentages increase to 75% (taking into account participation in APM-like models of other payors) for 2023 and later years.

The Act precludes administrative or judicial review of CMS’ decisions on whether one is a “qualifying APM participant” or a “eligible APM.” determination that a physician is a qualifying APM participant; a determination that an APM is an “eligible APM”; or a determination of the amount of the 5% APM incentive payment (including any estimation used to calculate the 5%).

The Act establishes a new committee called the Payment Model Technical Advisory Committee (TAC) to advise the Secretary on “physician-focused payment models.” The committee is composed of 11 members with expertise in “physician-focused payment models and related delivery of care” and up to 5 members may be “providers of services or suppliers” or their representatives.

Priorities and Funding for Measure Development

CMS has worked with the American Medical Association (AMA), physician associations representing primary care physicians and specialists, and the National Quality Forum (NQF) to develop hundreds of quality measures, with reporting requirements that depend on whether measures are reported via EHRs or administrative claims. The options for individual physicians to report PQRS measures vary depending on their scope of practice and practice size (and change annually), and their ability to gain bonuses and avoid penalties depends not only on one’s own behavior but on that of other physicians in one’s practice group.

The measure development process has been criticized by some who have argued that measure development is an unfunded mandate on organized medicine, that the measures do not accurately reflect the quality of care, and that the process for developing them is too slow. To address these concerns, Congress created a Qualified Clinical Data Registry (QCDR) which can be used to report quality measures.18 A QCDR must include data from multiple payers and give to participants timely performance data on transparent data elements, but the measures do not have to be endorsed by the NQF, streamlining the process of developing measures.

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18 Sec. 601(b) of the “American Taxpayer Relief Act of 2012” (P.L. 112-240).
The Secretary, with stakeholder input, must develop and publish a plan for the development of quality measures for use in the MIPS and in APMs. The Secretary must post a draft plan on the CMS website by January 1, 2016, finalizing it by May 1. The draft plan must take into account how measures from the private sector and integrated delivery systems could be used in Medicare and “how clinical best practices and clinical practice guidelines should be used” in developing quality measures.

In developing the draft plan, the Secretary must prioritize: (1) outcome measures; (2) patient experience measures (3) care coordination measures; and (4) “measures of appropriate use of services, including measures of over use.” The Secretary also must consider whether measures to be developed under these arrangements would be electronically specified and consider clinical practice guidelines (where they exist).

By May 1, 2017, and annually thereafter, the Secretary must report on the progress made in developing quality measures, including the number of measures developed, descriptions of the measures under development, a timeline for completion of such measures, and information on quality areas being considered for future measure development.

The funding for carrying out these activities will be $15 million annually for fiscal years 2015 through 2019 (to be transferred from the Part B trust fund). This funding will remain available through fiscal year 2022.

**Payment for Chronic Care Management Services**

In order to encourage the management of care for individuals with chronic conditions, the Secretary shall “make payment (as the Secretary determines to be appropriate)” for chronic care management services furnished beginning January 1, 2015, in effect making permanent reimbursement for the care management code that was established starting in 2015. To prevent duplicative payments, only one professional or group practice will receive payment for these services provided to an individual. CMS cannot require that providers perform an annual wellness visit or an initial preventive physical as a prerequisite and must conduct an education and outreach campaign to inform healthcare providers and beneficiaries of the benefits of chronic care management services, focusing on “encouraging participation by underserved rural populations and racial and ethnic minority populations.”

**Public Reporting of Physician Performance Data**

The legislation also requires the Secretary to continue, on an annual basis, reporting data on Medicare’s payments to individual physicians, and to integrate the data with the Physician Compare website
beginning in 2016. The information must at a minimum include data on the volume of services provided, submitted charges and payments, and a unique identifier for each physician or eligible professional. The data must be searchable by physician specialty, location, and types of services.

Section 105 of the Act permits “qualified entities” beginning July 1, 2016, to provide Medicare claims data and non-public analyses to new authorized users, including providers, suppliers, employers, health insurance issuers, medical societies and hospital associations, subject to certain privacy rules. Those entities may share the data for non-public uses, including creating quality and patient care improvement programs, but not for marketing purposes. Data use agreements will specify the privacy and security requirements that apply to the data, including any prohibitions on using such data to link to individually identifiable sources of information. If individually identified, providers shall have opportunity to appeal and correct errors under the process afforded to them under the existing QE data appeals process. The Act also provides for CMPs for breaches of data use agreements, but they appear only to be applicable to QEs.

The Secretary also is required, beginning July 1, 2016, to provide Medicare (and possibly Medicaid and CHIP) claims data to qualified clinical data registries, for a fee. This provision will allow the linking of registry data with clinical outcomes data. Public reporting of the findings is permissible so long as a provider or supplier has an opportunity to appeal and correct errors.

Providers Opting Out of Medicare

Under prior law, health care providers could opt-out of Medicare for a two-year period. The Act establishes an “indefinite, continuous automatic extension of opt-out election” for those providers, which only stops if they notify the Secretary 30 days before the end of the current opt-out period. Beginning February 1, 2016, the number and characteristics (e.g., specialty, geographic distribution, etc.) of those providers shall be posted on an HHS website.

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19 The ACA authorized creation of the qualified entity program under SSA section 1874(e) to expand availability of Medicare data to outside users. A “qualified entity” is “a public or private entity that—(A) is qualified (as determined by the Secretary) to use claims data to evaluate the performance of providers of services and suppliers on measures of quality, efficiency, effectiveness, and resource use; and (B) agrees to meet the requirements described in paragraph (4) and meets such other requirements as the Secretary may specify, such as ensuring security of data.”

20 We note that this process may be limited to identifying only “errors” in the data and not allow for any appeal beyond correcting such errors. Also, under 42 CFR 401.717 the qualified entity is supposed to give the provider or supplier 60 days advance notice of the data to be released and then to release the data after 60 days, even if the provider/supplier has requested a correction in the meantime and a correction has not occurred.
Gainsharing

The Act requires the Secretary and the Inspector General to report to Congress within 6 months of enactment recommending narrow and targeted legislative changes to existing fraud and abuse laws to permit gainsharing between physicians and hospitals that improve care and efficiency. The report is to discuss ownership interests, compensation arrangements, and whether a portion of any savings should accrue to Medicare. The report must discuss accountability, transparency and quality to limit inducements to stint on care. The Act eliminates civil money penalties for inducements to physicians who limit services that are not medically necessary.

Goals for Interoperability

The Act declares it a national objective to achieve “widespread interoperability” of EHRs by the end of 2018. It defines “widespread interoperability” and, if the Secretary determines that goal has not been met, requires a report to Congress that identifies barriers and recommendations to interoperability, including adjusting Medicare payments and decertifying EHR technology products. It amends the Social Security Act to prohibit EHR professionals and EHR hospitals from deliberately blocking information sharing with other EHR vendor products, and the Secretary must report to Congress on mechanisms to assist providers in comparing and selecting certified EHR technologies. It also requires a GAO report on barriers to expanded use of telemedicine and remote patient monitoring.

Limits on Liability

The legislation prohibits using “implementation of any guideline or other standard under any Federal health care provision” to establish the standard of care or duty of care owed by a health care professional to a patient in any medical malpractice or medical product liability action or claim, including relating to a health care provider’s prescription or provision of a drug. However, it does not preempt any state or common law governing medical professional or medical product liability actions or claims.

Title II—Medicare and Other Health Extenders

Title II extends several Medicare and public health programs that are set to expire on various dates starting in March 2015. Many of those have been recurring items in the annual (or more frequent) legislation needed to fix the SGR formula. Most recently, the Protecting Access to Medicare Act of 2014 (PAMA) included a package of temporary extenders.
Consistent with PAMA and other prior SGR legislation, H.R. 2 temporarily extends (until 2017 or 2018) the following programs: the geographic practice cost index (GPCI) floor; the therapy cap exceptions process; the ambulance add-on payment; the payment adjustment for low-volume hospitals; the Medicare dependent hospital program; the authority for Special Needs Plans (SNPs) in Medicare Advantage; funding for the National Quality Forum to develop quality measures; add-on payments for home health services provided in rural areas; and special programs that provide services to individuals with Type I diabetes, Native Americans, and families of children with disabilities. Other programs being extended promote abstinence, prevent teen pregnancy and HIV infection, train of low-income individuals for healthcare jobs, and fund home visiting programs for mothers, infants and children.

H.R. 2 makes permanent two programs that assist low-income individuals with healthcare costs. Section 211 permanently extends the Qualifying Individual (QI) program, which assists low-income Medicare beneficiaries with incomes between 120 percent and 135 percent of the federal poverty level (currently from $14,124 to $15,890 per year) in paying their Medicare Part B premiums. According to the Congressional Budget Office (CBO), the QI program will increase Medicare spending by $14.6 billion over the next decade. Section 212 makes permanent the transitional medical assistance (TMA) program, which allows low-income families to maintain their Medicaid coverage for up to one year as they transition from welfare to work.

Section 221 extends, through fiscal year 2017, the Affordable Care Act’s additional funding for Community Health Centers (CHC) and National Health Service Corps (NHSC), increasing federal spending by $8.0 billion over the next ten years. This section also continues funding for residency training in community-based primary care settings.

H.R. 2 does not extend the one-year delay in implementation of ICD-10\textsuperscript{21} in the United States that was included in PAMA, meaning that the Congress has most probably foregone its opportunity to intervene again. Implementation of ICD-10 is set to start on October 1, 2015.

\textsuperscript{21} The ICD-9 code sets used to report medical diagnoses and inpatient procedures will be replaced by ICD-10 code sets on October 1, 2015. ICD-10 consists of two parts, 1) ICD-10-CM diagnosis coding which is for use in all U.S. health care settings and 2) ICD-10-PCS inpatient procedure coding which is for use in U.S. hospital settings.
Title III—2-Year Extension of the Children’s Health Insurance Program (CHIP)

Title III of H.R. 2 funds CHIP for another two years. CHIP covers more than 8 million children and pregnant women whose families have incomes above Medicaid eligibility levels. The federal government pays a higher matching rate for CHIP (the federal share averages 70% under CHIP vs. 57% for Medicaid), and states have more flexibility in the design of CHIP benefits and cost-sharing. The ACA extended funding for CHIP until September 30, 2015, and requires states to maintain the levels of eligibility for Medicaid and CHIP that were in place in March 2010 through September 30, 2019. While some in Congress argued for extending CHIP funding for the full four years, H.R. 2’s funding of CHIP expires on September 30, 2017.

This provision preserves, through FY 2017, the qualifying states option. That program increases the state CHIP allotments for states that had provided coverage to CHIP-eligible children prior to the enactment of CHIP in 1997. It also maintains, through FY 2017, the CHIP Contingency Fund, which is available to states if they experience a funding shortfall. (Unlike Medicaid, CHIP’s funding is capped.) It also extends grants currently available under CHIP to enable states to address barriers to enrollment.

Finally, it extends the Express Lane eligibility program, which permits states to rely on findings from designated Express Lane programs, such as the federal School Lunch, Head Start, and WIC programs, to facilitate those children’s enrollment in CHIP.

Title IV—Offsets

The Act includes spending decreases (affecting primarily hospitals and post-acute care providers) and increases in premiums paid by high-income Medicare beneficiaries that are estimated to total $73 billion over 10 years. (These provisions partially offset the Act’s estimated costs; the Act is estimated to increase the deficit by $141 billion over 10 years.) Offsets do not directly affect the pharmaceutical industry.

Beginning in 2020, Sec. 401 limits Medigap plan coverage of beneficiary cost-sharing for newly eligible Medicare beneficiaries to amounts above the Part B deductible (currently $147/month). Two Medigap plans currently provide “first dollar” coverage, which induces beneficiaries to use more services than they otherwise would. The provision does not affect beneficiaries who are enrolled in Medicare Advantage plans or buy Medigap insurance in certain states.

Beginning in 2018, beneficiaries with modified adjusted gross incomes (MAGIs) between $133,501 and $160,000 will pay for 65% of their premiums and those with MAGIs above $160,000 will pay 80%. (Until 2018, those thresholds are 50% for $100,000 to $150,000, 65% for $150,000 to $200,000, and 80% for $200,000 and above.) Starting in 2020, the income thresholds will be indexed to grow at the same rate as the consumer price index (CPI). Together, CBO estimates that this provision and Sec. 401 will save $34.3 billion -- almost half of the $73 billion in total offsets included in H.R. 2.

Title IV also cuts Medicare payments to hospitals and post-acute care providers. It replaces a scheduled 2018 increase in hospital payment rates of 3.2% with annual increases of 0.5% per year from 2018 to 2023 (saving $15.1 billion). It also caps at 1% the annual updates to Medicare’s payment rates for certain providers of post-acute-care and long-term-care services in 2018 (saving $15.4 billion).

Section 413 permits the IRS to recoup up to 100 percent of federal payments to Medicare providers that have unpaid taxes. Prior law limited such levies to 30 percent.

The Act also changes state allotments for Medicaid disproportionate share hospital (DSH) payments such that allotments will be higher in the next few years, and lower in later years, when compared to the schedule of payments in current law.

The Act makes permanent a transitional medical assistance provision that requires states to continue Medicaid coverage for certain families whose incomes increase above the Medicaid eligibility level. According to CBO, the increased costs for Medicaid will be more than offset by savings for exchanges and employers, saving the federal government net $2.8 billion.

**Title V: Protecting the Integrity of Medicare and Miscellaneous**

Title V includes several provisions that aim to prevent fraud and reduce improper Medicare payments. It prohibits inclusion of beneficiaries’ Social Security numbers on their Medicare cards to reduce identity theft. It requires CMS to deploy information technology, such as implementing “smart cards” and sending Medicare statements to newly eligible beneficiaries electronically rather than by mail. Further, CMS must ensure that Medicare does not pay for services for deceased individuals, and that valid provider National Provider Identifiers (NPIs) appear on pharmacy claims to receive payment. H.R. 2 also extends the contract term for Medicare Administrative Contractors (MACs) from 5 to 10 years, but requires CMS to increase transparency around MAC performance.
H.R. 2 also adds a requirement for MACs to establish an “improper payment outreach and education program” under which recovery audit contractors (RACs) will share with MACs information on improper payments that were made to providers in the region. A provider will receive from its local MAC a list of the most frequent and expensive payment errors it made in the past quarter and instructions for preventing them.\footnote{This provision explicitly authorizes in statute tactics that some MACs have begun using to educate physicians about the volume of diagnostic tests they perform and the frequency with which they use “special stains.” \url{http://pathologyblawg.com/pathology-news/pathology-law/healthcare-fraud-pathology/palmetto-gba-defining-pathology-medicare-fraud-new-standards/}.} In establishing the improper payment outreach programs, MACs will prioritize items and services that are most frequent, most costly, clearly inadvertent, and those “due to clear misapplication or misinterpretation of Medicare policies.”

One area of potential future enforcement action with this “misinterpretation of Medicare policies” authority is further scrutiny of payments for those off-label uses of drugs and biologics that are not covered. Further, the MolDx program, which makes coverage decisions for Medicare on molecular diagnostic tests, recently finalized a local coverage determination that identifies several uses of immunohistochemistry testing that are not reasonable and necessary for use as companion diagnostics in the selection of oncology drugs and biologics.\footnote{See “MolDX: Special Histochemical Stains and Immunohistochemical Stains (L35693),” available at \url{http://www.cms.gov/}.}

Other provisions of the Act respond to advocacy from stakeholders. H.R. 2 extends, through September 30, 2015, the MACs’ “probe and educate” program to assess provider understanding and compliance with the “two-midnight rule,” on a pre-payment basis. It also extends the PAMA prohibition on post-payment RAC audits for certain dates of service. Because the two-midnights rule affects inpatient/outpatient status, this provision may have implications for the availability of 340B discounts, which are limited to outpatient covered drugs.

The Act also reverses CMS’ decision to eliminate global 10- and 90-day surgical packages (under which only same-day, related services would have been bundled.) Starting in 2017, it requires CMS to begin collecting data for valuing surgical services from new sources; starting in 2019, CMS must use the new data to value surgical services on the Medicare physician fee schedule. (Changes in relative value units for surgical services (RVUs) will affect payment rates for other services.) Beginning on or before January 1, 2019 (but no earlier than January 1, 2017), the Secretary will require that bidders in the competitive acquisition program for durable medical equipment demonstrate that they are state licensed, as required in the states in which they do business, and to post a surety bond of...
$50,000 to $100,000 for each geographic area for which they intend to submit a bid. If a bidder’s bid is at or below the median bid, is offered a contract, and does not agree to sign it, the Secretary will collect the surety bond.

The Act also requires the Secretary to publish guidance clarifying how the “Common Rule” for human subjects participating in medical research will apply to clinical data registries used for quality improvement. Finally, the Act expands the prior authorization process for “repetitive scheduled non-emergent ambulance transports” from the current CMS Innovation Center project in three states to a national program starting in 2017, and establishes a prior authorization program for chiropractors whose billing patterns are outside the normal range.

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