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Background: Regulatory Sprint to Coordinated Care

In June 2018, Health and Human Services (HHS) Deputy Secretary Eric Hargan announced a regulatory reform initiative entitled the "Sprint to Coordinated Care." This effort is focused on identifying regulatory requirements and/or prohibitions that may act as barriers or pose undue burdens to the delivery of better value and care for patients. HHS has identified the following four areas for potential reform:

1. The Physician Self-Referral Law ("Stark Law")
2. The Anti-Kickback Statute (AKS) and beneficiary inducement prohibition to the Civil Monetary Penalty law (CMP)
3. The Health Insurance Portability and Accountability Act (HIPPA)
4. 42 C.F.R. part 2 – substance abuse confidentiality and sharing information

Of particular interest to many healthcare stakeholders are the barriers within the Stark and Anti-Kickback Laws that have created unnecessary obstacles, both real and perceived, to care coordination and new value-based models. This roundtable is focused on these two laws and potential improvements that could be spearheaded by HHS or through other avenues.

The Stark Law

HHS identified the Stark Law as the Regulatory Sprint's first target, issuing a Request for Information (RFI) to stakeholders on June 25, 2018. The Stark Law's intended purpose is to reduce potential conflict between a physician's health care decision making and the physician's financial interests. The law, however, was designed in a fee-for-service environment and can be a point of tension for value-based payment models and other efforts that seek to promote care coordination or establish financial incentives for physicians. While the law includes certain exceptions, many stakeholders have found these to be too narrow or overly complex to facilitate efforts aimed at improving care for patients. In addition, since the Stark Law is a strict liability statute, mere noncompliance with an exception can create potential liability, which often deters stakeholders from engaging in certain practices, even if they could benefit patients and promote coordination.

To address these barriers, HHS asked for stakeholder comments, including on the following points:

- The creation of new exceptions to the Stark Law to facilitate value-based and/or coordinated care models;
- Possible approaches to defining key terms such as "commercial reasonableness," "fair market value," and "taking into account the volume or value of referrals";

- The applicability and utility of current exceptions for APMs and other novel models.

The AKS and CMP

On August 27, 2018, HHS in coordination with the Office of Inspector General (OIG) published a second RFI seeking comment on the AKS and the exceptions to the CMP as they relate to the shift towards value-based payment systems and coordinated care. Unlike the Stark Law, the AKS and CMP prohibitions go beyond physicians and can create challenges across a host of stakeholders, including hospitals, manufacturers, suppliers and other entities.

HHS specifically sought input on the following issues:

- Details about new types of arrangements the industry is pursuing to promote care coordination, value-based payment, APMs, innovative technology and other novel financial arrangements;
- Definitions of key terms, such as "value," "clinical integration," "risk-sharing" and others;
- Types of beneficiary engagement incentives and cost-sharing initiatives used by providers, suppliers and others and how they may improve quality of care, care coordination and patient engagement;
- Current fraud and abuse waivers available for certain APMs and whether they are burdensome or helpful; and
- The intersection of the Stark Law and the AKS and when these laws should have parallel exceptions or safe harbors and when they should not.

The Administration is now working to finalize proposed regulations to address both the Stark and AKS requirements, and it is anticipated that these rules could be released in July/August.

External Participants for Stark/Anti-Kickback Roundtable

Jeff Bromme, General Counsel of Advent Health

Jeffrey Bromme serves as Executive Vice President and Chief Legal Officer at Advent Health, a large non-profit, Florida-based health care system with operations in nine states. He leads the department providing legal services to Advent providers, the advocacy and policy departments, and tax department. He previously served as General Counsel to the U.S. Consumer Product Safety Commission, clerked for the Honorable Will Garwood, U.S. Fifth Circuit Court of Appeals. Bromme earned his JD from the University of Texas School of Law, and a BA from Southwestern Adventist University.

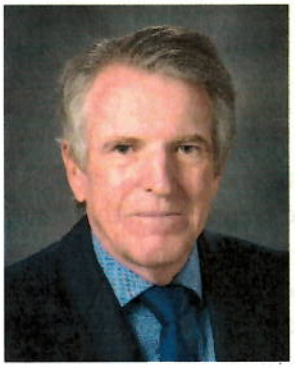
Blair Childs, Senior Vice President of Premier

Blair Childs is considered a national expert in health policy, advocacy, and reform. He currently serves as the Senior Vice President of Public Affairs at Premier, having previously been Executive Vice President of Strategic Planning and Implementation at AdvaMed. Blair has been at the center of health care policy issues in Washington for over two decades, leading reform efforts on the state and national level. He is a graduate of Middlebury College.

Brian Connell, Executive Director of Federal Affairs at Leukemia and Lymphoma Society

Brian Connell is the Executive Director of Federal Affairs for the Leukemia and Lymphoma Society. He has experience leading legislative strategy and coalition-building for non-profits, industry groups, and government. Connell started his career working in Congressional offices, eventually moving on to work as the Director of Government Relations for the Medical Imaging and Technology Alliance. He holds a BA in Political Science from Evansville University.

Tom Feeley, Senior Fellow, Harvard Business School



Thomas Feeley, M.D. is a Senior Fellow at Harvard Business School (HBS) and Professor Emeritus at the University of Texas MD Anderson Cancer Center. At HBS he is involved in research and education of value-based health care in the Institute for Strategy and Competitiveness with Harvard University Professor Michael Porter. At the University of Texas, Feeley was the Helen Shafer Fly Distinguished Professor of Anesthesiology, and headed their programs in anesthesiology and critical care and their Institute for Cancer Care Innovation. Feeley is a prolific author and researcher in health care outcomes, value-based systems, and information technology. His clinical background is in anesthesiology and critical care. Feeley earned his MD and BA at Boston University.

Kerri Gordon, Vice President for Government and External Affairs, Allina

Kerri joined Allina Health in March of 2010. In her role as Vice President of Government and External Relations, Kerri oversees all local, state and federal public policy efforts on behalf of Allina Health. Prior to her work at Allina, Kerri oversaw public affairs for Clearway Minnesota. Previous work included lobbying for a firm in Washington, D.C., and working for the Minnesota Senate. In 2002, Gordon received her Masters in Public Policy from the Hubert H. Humphrey Institute of Public Affairs at the University of Minnesota. Gordon attended American University in Washington, DC where she earned her undergraduate degree.

Mary Grealy, President, Healthcare Leadership Council

Mary Grealy is the President of the Healthcare Leadership Council, a policy advocacy group representing all sectors of the industry. She has led efforts to reform Medicare and improve care quality at several industry groups in her career. She has been ranked multiple times in Modern Healthcare as one of the 100 Most Powerful People in Healthcare and was named in their Top 25 Women in Healthcare in 2009. Grealy holds a JD from Duquesne University School of Law, and a BA from Michigan State University.

Saliha Greff, Vice President and General Counsel, Respiratory, Gastrointestinal and Informatics, Medtronic

Saliha Greff is the VP and General Counsel in the Respiratory, Gastrointestinal, and Informatics division of Medtronic, the world's largest medical device company. She was previously the Chief Compliance Officer for both the Respiratory and Monitoring Solutions and Vascular Solutions businesses at Covidien, which was acquired by Medtronic in 2014. Greff earned a JD from Syracuse University College of Law, an MPH from Harvard, and a BA from University of Michigan.

Jorge Lopez, Jr. Executive Vice President and General Counsel of Memorial Sloan Kettering Cancer Center

Jorge Lopez, Jr. serves as General Counsel at Memorial Sloan Kettering, a world-renowned cancer hospital based in New York City. He has decades of experience advising on health care regulatory issues, industry issues, and policy, particularly related to cancer care. Lopez was previously a longtime partner at Akin Gump Strauss Hauer & Feld, a large international law firm. He earned his JD at Harvard Law School, and a Masters in Economics and BA in Economics from the Catholic University of America.

Gregory Poulsen, Senior Vice President, Intermountain Healthcare

Gregory P. Poulsen, M.B.A., is Senior Vice President for Intermountain Healthcare. As a member of Intermountain's four-member management committee, he shares responsibility for the operational and strategic issues of the organization. Mr. Poulsen has direct responsibility for strategic planning, research and development, marketing, information technology, and e-business at Intermountain, which he joined in 1982. Mr. Poulsen received his bachelor's degrees in physics and biology, and a master's degree in business administration, from Brigham Young University.

Joyce Rogers, Chief Government Affairs Officer, Advocate Aurora Health

Joyce Rogers serves as the Chief Government Affairs Officer at Advocate Aurora Health. Previously, she worked at AARP, serving as a senior vice president of government affairs, where she led federal and state advocacy for the organization, Rogers has worked in government affairs for over 20 years in Washington, preceded by time working in the House of Representatives. Joyce received her JD from the University of Pennsylvania and her BA from Williams College.

Nick Turkal, CEO of Advocate Aurora Health

Nick Turkal is the President and CEO of Advocate Aurora Health, an integrated health care system serving Wisconsin and Illinois. He continues to practice medicine as a family physician while serving in this position. Turkal has been named one of the 100 Most Influential People in Healthcare and one of the 50 Most Influential Physician Executives by Modern Healthcare. Prior to joining Aurora Health Care (now Advocate Aurora), he served as a clinical professor and Dean of University of Wisconsin-Madison's medical school. Turkal received his MD and BA from Creighton University.

Chris White, General Counsel of AdvaMed

Christopher White is the Chief Operating Officer, General Counsel, and Secretary of AdvaMed. White has worked on issues in health care regulatory compliance, fraud, and abuse for over 30 years in Washington. He is a frequent speaker and guest writer on health industry issues. White received his JD from Catholic University Law School, and his BA from Wake Forest University.

Policy Proposals to Advance Value-Based Health Care

AdvaMed
Advanced Medical Technology Association

BACKGROUND

It is widely recognized that the U.S. health care system must transition from a fee-for-service/ fee-for-product (volume-based) payment framework to a value-based paradigm to achieve better clinical outcomes, lower costs and improve the patient experience. Value-Based Arrangements (VBAs) condition or modify payment based upon the results achieved (clinical, cost, and/or patient experience outcomes). In a VBA, there is shared accountability (e.g., between medtech companies and health care providers) for both clinical outcomes and the total cost of care.

Providers, payors and industry are deterred from participating in VBAs by a 1972 statute and its regulatory safe harbors that were designed for the fee-for-service framework--the federal Anti-Kickback Statute (AKS) (42 USC § 1320a-7b(b)) and its safe harbor regulations (42 CFR 1001.952) need modernization to enable broader, more extensive, and more patient-centered VBAs.

The AKS prohibits offering or providing anything of value to incentivize or reward the use of any service or item covered in part by a federal program. Aspects of VBAs at tension with the AKS include: (1) the services that must be bundled to develop and operationalize the VBA (e.g., data collection, tracking, analysis, reporting); (2) the services and technologies that are a part of the solution to achieve the targeted outcome (e.g., care coordination, monitoring, optimizing care pathways, and technology integration to help clinicians make needed interventions); and (3) elements of outcomes-based pricing, warranties, and risk-sharing.

RECOMMENDATION – NEW VALUE-BASED AKS SAFE HARBORS

To promote broader, more comprehensive engagement in patient-centered Value-Based Arrangements, AdvaMed recommends creating three new value-based AKS safe harbors—

(1) **A Value-Based Pricing Arrangements (VBPA) Safe Harbor** - that would allow for price adjustments (e.g., front-end discount, rebate, performance or incentive payment) based on the achievement of a measurable clinical, cost, and/or patient experience outcome. In other words, the "end price" (or net payment) would be dependent on the results.

(2) **A Value-Based Warranty (VBW) Safe Harbor** – that would allow manufacturers or providers to make certain clinical and/or cost outcome assurances and provide an appropriate remedy where such outcomes are not achieved. Such an outcome warranty would allow a manufacturer to share risk by providing a payment, item, and/or service when a warranted clinical or economic outcome is not achieved, including providing alternative, complementary, or supplemental items / services. For example, if warranted outcome is not achieved, this safe harbor would allow the seller to cover all or part of amounts the buyer owes or fails to receive, or costs otherwise borne by the buyer as a result of a solution not achieving the warranted outcome.

(3) **A Value-Based Risk-Sharing Arrangements Safe Harbor** – that would allow for providing services to improve clinical outcomes and/or reduce costs on risk-share payment terms where the net compensation is based on whether clinical and/or cost improvements were actually realized. The key difference relative to the other safe harbor proposals is that these services would be provided independent of any reimbursable items or services and here the proposed framework would allow for multiple manufacturers to share risk with payors, providers, and other entities like data aggregators.

For additional information visit: www.advamed.org/VBHC

MODERNIZING STARK LAW AND REDUCING REGULATORY BURDEN

The Healthcare industry supports modernization of the Physician Self-Referral Law (also known as the "Stark Law") to eliminate the regulatory barriers it is imposing on patients and care coordination. When enacted in 19898, the Stark Law's intention was to curb self-referral, inappropriate financial incentives, and over-utilization in Medicare. In principle, the law was well-intended for a world centered on fee-for-service care (FFS). Now, in 2019, this same law often impedes value-based (VB) models and care innovations by restricting essential care coordination, creating financial barriers, and mandating complex regulatory requirements.

With the shift from FFS to VB models, hospitals and providers are more accountable than ever for financial and patient outcomes across the entire continuum of care, and this collective accountability requires all players in the health care system to work together in new ways. We are therefore highly supportive of the U.S. Department of Health and Human Services' regulatory efforts to modernize the Stark Law. Specifically, we support the following areas, which fall under three distinct categories:

(1) Create a Value-Based Arrangements Exception: The exception would protect all arrangements where compensation is reasonably related to value-based goals, such as bundled payment models and Accountable Care Organizations, where there is shared accountability for clinical outcomes and cost of care. This would avoid creating separate exceptions for different types of models, which only adds complexity to compliance requirements.

(2) Provide Clarifying Language: We request the Administration to provide clarity on three key terms – "fair market value," "volume and value of referrals," and "commercial reasonableness" – that are commonly used in Stark Law exceptions. These terms should be designed to, as clearly as possible, create a bright-line rule that providers can use to ensure they are compliant.

(3) Make Technical Changes to Reduce Burdens on Providers While Protecting Patients and Taxpayer Resources: HHS should focus resources on violations that directly harm beneficiaries, as opposed to mere technical violations. In particular, we urge:

- Improving the advisory opinion process to clarify and give certainty to providers regarding the proper interpretation of the regulations;
- Mitigating enforcement of technical violations that pose little or no harm to beneficiaries (e.g., compliance with signature requirements).

For more information please contact Tony Curry, Director of Federal Affairs at Advocate Aurora Health: (414) 299-1657

Brent C. James, MD, is Intermountain Healthcare's chief quality officer and leads the Intermountain Institute for Healthcare Delivery Research. He is a member of the National Academy of Medicine and a professor of clinical medicine (affiliated) at the Stanford University School of Medicine. He holds adjunct faculty appointments at the Harvard School of Public Health and the University of Utah School of Medicine. **Gregory P. Poulsen** is Intermountain Healthcare's senior vice president and chief strategy officer. He is a trustee of the American Board of Internal Medicine Foundation and a national guest scholar at the Stanford University School of Medicine.

FIXING HEALTH CARE

The Case for Capitation

It's the only way to cut waste while improving quality.

BY BRENT C. JAMES AND GREGORY P. POULSEN

To rein in health care costs in the United States, we should look to the ideas of W. Edwards Deming, the legendary management guru who showed companies how to cut waste from work processes and lower operating costs by improving quality. Recent studies using Deming's approach reveal that

PETER CROWTHER

inadequate, unnecessary, uncoordinated, and inefficient care and suboptimal business processes eat up at least 35%—and maybe over 50%—of the more than $3 trillion that the country spends annually on health care. That suggests more than $1 trillion is being squandered.

Ongoing reform efforts by the federal government and private insurers have had some success in prodding health care providers to improve quality and reduce waste. But it's far from certain that they'll be enough. Even after taking existing and proposed reform initiatives into account, federal projections show health care expenditures consuming larger and larger proportions of the GDP. Moreover, under the prevailing payment models, which are based on volume of services, providers often don't receive any of the savings from waste reduction, which undermines both their financial health and their ability to continue to invest in such efforts.

The solution to this quandary is to change the way businesses, government, and other purchasers pay for health care to population-based payment. Under this approach, providers receive a fixed per person (or "capitated") payment that covers all health care services over a defined time period, adjusted for each patient's expected needs, and are also held accountable for high-quality outcomes. It's the only payment system that fully aligns providers' financial incentives with the goal of eliminating all major categories of waste. It fundamentally shifts the role of managing the amount, form, and cost of care from insurers to medical practitioners. It also ensures that providers receive enough of the savings that they can afford to fund the changes needed to bring down costs.

A population-based payment model also has major implications for pure health insurers: Because it removes care oversight from their purview, it leaves them only traditional insurance functions such as claims processing, risk analysis, reinsurance, marketing, and customer service. Many nonprofit health insurers competently provide a full range of such services for less than 10% of total health insurance payments, well below the portion that many health insurers now extract through current systems.

In this article we'll look at the different categories of waste in health care and then outline the various payment methods that have evolved in the United States and their effect on waste. We'll then demonstrate how population-based payment, backed by good reporting, can improve clinical results, eliminate unnecessary spending, and lower costs.

Three Kinds of Waste

In health care there are three basic categories of waste: production-level waste, case-level waste, and population-level waste.

The first category involves inefficiencies in producing "units of care"—drugs, lab tests, x-rays, hours of nursing support, and any other item consumed in patient treatment. It accounts for about 5% of total health care waste. Eliminating it requires things like negotiating down prices for supplies, lowering handling and storage costs, streamlining processes for producing lab tests or x-rays, and reducing losses due to damage, misplacement, or expiration.

The second category, which comprises about half of all waste in care delivery, is unnecessary or suboptimal use of care during a hospital stay, an outpatient visit, or some other treatment episode, or "case." Examples include redundant x-rays ordered when the original images couldn't be found, duplicate lab tests ordered because a physician didn't know that someone else had already done the tests, and medications prescribed to treat avoidable complications.

The third category, which accounts for about 45% of total waste, involves cases within a patient population that are unnecessary or preventable. It includes end-of-life intensive care given to people who've expressly asked not to receive it; elective surgical procedures that, with better information, patients would have forgone; and visits to specialists or hospitalizations that could have been avoided through timely, cheaper outpatient care. Waste here obviously feeds waste at the other two levels, since each unnecessary or avoidable case consumes care.

The Impact of Different Payment Models

To understand what's driving up health care spending, it's critical to examine whether—and to what extent—health care payment methods encourage or discourage waste reduction. An optimal payment method must address two important challenges.

Idea in Brief

THE PROBLEM
Despite ongoing reform efforts, U.S. expenditures on health care as a percentage of GDP are still rising. And at least 35%, or more than $1 trillion, of the amount spent annually on health care is waste.

THE ROOT CAUSE
Under the prevailing fee-for-service and per case payment methods, health care providers don't get the savings generated by their efforts to reduce waste, which undermines their financial health and their ability to invest in programs that cut costs by improving quality.

THE SOLUTION
Replace existing methods with a form of capitation that would pay care delivery groups directly for covering all of an individual's health care needs for a defined time period. This would greatly reduce the role of pure insurers. The Intermountain nonprofit health care system has demonstrated that this approach works.

One is how to divvy up the savings generated by eliminating waste. If most or all of the money goes to health care payers, providers have no incentive to cut waste. If most or all of it goes to providers, how do you ensure that they pass on some of it to customers—especially if there is no efficient market, which, we'd argue, you often can't create in health care because of its complexities? Another issue is how a payment method affects the power of patients and their physicians to make decisions that are in patients' best interests. Let's look at the methods that have evolved in the United States over the years and see how each stacks up.

Cost-plus. In 1965, as part of the War on Poverty, the U.S. Congress enacted the Medicare and Medicaid government-funded health insurance programs. Those programs paid physicians and hospitals on a cost-plus basis. Care providers estimated their cost for delivering each unit of care, and then the government paid that cost plus a markup. The result was that providers could basically consume whatever resources they wanted—and had no incentive to reduce spending. Today cost-plus payment persists only in small pockets of health care, such as some specialty hospitals and some small rural hospitals.

Fee for service. Until the 1980s there was little standardization in the way hospitals and physicians billed payers for individual units of care such as lab tests, supplies, or medical services. Then, in a bid to control costs, Medicare began to organize some of the fee categories, and a degree of standardization emerged for the prices and nomenclature of most items, for commercial as well as government payers.

Under the fee-for-service payment method, a provider supplies an approved billing code for (and may be required to justify) each unit of care consumed during a hospitalization, same-day procedure, or outpatient visit. It cannot bill for anything that lacks a code. For each billed item the government pays the lesser of the group's actual billed charges or a federal maximum allowed rate. (The method it uses to calculate that rate isn't strongly linked to true underlying costs and is controversial.) As a result, care delivery groups try to ensure that their billed charges are above the federal rates. Given that the rates change constantly as the government updates its estimates, the easiest way for a group to guarantee maximum payment is to set high prices for everything.

Fee for service also encourages care deliverers to provide as much care as possible, regardless of whether it's all necessary or optimal. Because of that, the types and volume of care used to treat a given disease vary widely, making it difficult to compare the true cost of care across providers. As a result, commercial insurers often base purchasing decisions on percentage discounts they've negotiated with care delivery groups. That in turn leads some groups to apply very high markups—so that they can offer large discounts to the insurers.

> Half of all waste in care delivery is unnecessary or suboptimal care—such as redundant x-rays or medications to treat avoidable complications.

Fee for service neither effectively promotes the elimination of all kinds of waste nor allocates savings among providers, payers, and patients in a way that would fuel continual improvements. Despite its widely acknowledged deficiencies, it remains the most common payment method in the United States. It forms the basis for nearly all accounting systems used by care delivery groups and health care insurers.

Per case. This payment method dates back to 1983, when the federal government introduced the "diagnosis-related group" (DRG) system for Medicare patients. Again, the primary purpose was cost control. Currently, DRGs classify hospital and same-day surgery patients into 753 unique categories, on the basis of each patient's primary disease, specific treatment, secondary chronic conditions, and care intensity. For example, DRG 7 is a lung transplant, DRG 179 uncomplicated pneumonia, and DRG 343 a simple appendectomy. Medicare pays facilities, such as hospitals or surgery centers, a flat rate per case in each category. Meanwhile, it pays physicians involved in the same cases on a fee-for-service basis. Commercial insurers sometimes pay hospitals and surgery centers per case but pay the physicians providing treatment via fee for service.

In 2016 the government introduced "bundled" per case payments in its Medicare program, following an approach first tried by a handful of commercial health insurers. The initial federal experiment focuses on total hip- and total knee-joint-replacement surgery. It extends the single flat-rate DRG payment to include all physician fees and all costs of any related treatments, complications, or hospital readmissions within 90 days of the original operation. If the experiment successfully reduces costs, the government plans to extend it to other types of cases.

Per case payment gives providers incentives to improve efficiency within cases but, like fee for service, is a volume-based system that fuels waste. The more cases a care delivery group handles, the more it gets paid. Therefore, it's in the group's financial interest to maximize the number of cases it treats, even if some add no value or actively harm patients.

Capitation. In contrast to fee-for-service and per case payment methods, per person payment methods can encourage waste reduction at all three levels and give patients and physicians the freedom to make the treatment decisions they think are best. But to function well, such systems must adjust payments for risk, which is easier to do at the level of a population than of an individual patient. (A typical population is a business's employees and their dependents.) There have to be quality measures to ensure that providers don't withhold necessary care. And finally, savings from waste reduction must go back to care delivery groups to keep them financially viable.

The last widespread use of capitation in the U.S. didn't meet the last two criteria. In the late 1980s and into the 1990s, both government and private payers looked for ways to reduce health care inflation. The primary mechanism they turned to was health maintenance organizations (HMOs), which were usually owned and managed by insurance companies. While employers generally paid HMOs on a capitated basis, most HMOs continued to pay care delivery groups using fee-for-service and per case methods.

HMOs employed a series of tools to limit health care consumption. For example, many mandated that primary care physicians act as gatekeepers. Care providers had to get permission from nurses and doctors based at insurance companies to make referrals to specialists and order surgical procedures, imaging, and hospitalizations. In some instances the HMOs passed along a portion of the capitated insurance payment to the provider groups to cover all necessary services, which transferred the financial risk to them.

HMOs succeeded in curbing expenditures. Health care costs as a proportion of GDP remained flat from 1993 through 2000—even though one reason was that the GDP was growing rapidly, hiding the price increases that did occur. However, the insurance companies weren't in the best position to make health care decisions, because they were removed from patient-clinician interactions. The HMOs' bureaucratic controls imposed hassles and treatment delays. Some physician groups, unable to manage care costs after accepting capitated payments, failed financially. Patients and physicians rebelled, arguing that the financial incentives built into capitated payments led HMOs to ration care and accusing insurance companies of putting profits before patients' health. The resulting political backlash ended insurance-company-based cost control as a national movement.

A Better Capitation Model

A population-based payment system would differ from the capitated method most insurance companies use in significant ways. With PBP, care provider organizations would receive a risk-adjusted monthly payment that covers all necessary health services for each person. Eliminating the gatekeeper and the third-party authorization for care that made HMOs so unpopular, PBP would put responsibility for considering the cost of treatment options in the hands of physicians as they consult with patients. Finally, unlike HMOs of the 1990s, PBP would include quality measures and standards. A care delivery group would pay independent physicians using existing

fee-for-service mechanisms but would adjust payments quarterly according to the levels of clinical quality and patient satisfaction achieved as well as total cost to care for the covered population. The advantage of this approach is that it would build on a system physicians already understand while rewarding them for improvements in quality and cost, which would compensate them for income lost if total care volumes decline as a result of waste elimination.

Federal cost control efforts mandated by the Affordable Care Act of 2010 are pushing health care payments in this direction. Recognizing that volume-based payments fuel expenditures, increase waste, and potentially worsen quality, government officials are moving toward "pay for value" systems, which give providers financial incentives to hold costs down by improving clinical outcomes and patient satisfaction. To do this, they're implementing the initiatives below—each of which represents a step along the spectrum toward full capitated payment:

- Mandatory reporting of quality and patient satisfaction for all care delivered under Medicare, with financial penalties for care delivery groups that don't meet standards or that rank poorly compared with other groups.
- The Medicare bundled payment experiment launched this year.
- The Medicare Shared Savings Program, under which a care delivery group is paid via traditional fee for service and per case DRGs but receives a portion of any savings it achieves through care coordination and waste reduction.
- Alternative payment models, including patient-centered medical homes and accountable care organizations (ACOs) for Medicare patients. These programs also pay via fee for service and per case but give care delivery groups a potentially larger share of the savings, provided their charges come in under preset spending levels. However, if charges exceed the preset levels, care delivery groups may have to absorb them.
- Full capitated payment. The federal government is launching "next-generation ACOs," in which a care delivery group receives a monthly capitated payment that covers all health services for Medicare patients enrolled with it, adjusted for their expected health needs. Different care delivery groups (including our organization, Intermountain Healthcare) are proposing—and the government is likely to approve—different forms. It may take a few years, after these experiments produce results, for the definitive form to emerge.

We recommend that, where possible, care providers jump directly to population-based payment and that payers actively support them in that move. Of the pay-for-value methods just listed, it's the only one that gives care delivery groups the financial incentives to attack all three levels of waste. More specifically, it's the only one that ensures that care delivery groups capture enough of the savings from waste elimination that they stay financially viable and can continue to invest in such programs. Let us explain.

To raise quality and eliminate waste in health care, we need to do more than end production inefficiencies and unnecessary or inappropriate treatments. Care providers also have to develop, test, and repeatedly improve new care delivery processes—and that requires investment. A major problem with fee-for-service and per case payments is that they redirect the savings away from those who must make the investment and into the pockets of insurance companies. Consider these two examples:

> To raise quality and eliminate waste, care providers have to develop innovative new processes—and that requires investment.

Congestive heart failure and ischemic heart disease (compromised blood flow to the heart) are very common conditions, especially among Medicare patients. Certain medications (beta blockers and ACE and ARB inhibitors), taken every day, can stabilize patients' conditions and prevent death. The key is recognizing which people need the medications and getting them started on them.

Nationwide, hospitals prescribe the right long-term medications for these two conditions to their patients only 44% of the time. Intermountain Healthcare's LDS Hospital in Salt Lake City developed a system that boosted its accuracy rate from 57% to over 98%. As a result, mortality fell by more than 450 deaths a year, and hospitalizations by almost 900 cases a year. The majority of those cases were paid through Medicare, on the per case DRG system. The lower hospitalization rate meant that LDS Hospital lost $3.2 million a year in revenues, along with associated operating income.

From a purely financial viewpoint, its investment in improving patient outcomes and lowering costs worked out very poorly indeed.

Intermountain's American Fork Hospital had a large birthing service. About 110 of its newborns each year were borderline premature—with a 34- to 37-week gestation versus the normal 40 weeks. Often the lungs of premature babies are not fully developed, which means they can collapse. In the distant past, most of these "blue babies" died. Then clinicians learned to place a breathing tube through an infant's mouth into its major airway and use a mechanical ventilator to keep the lungs inflated for a few weeks. This gave infants' lungs time to mature, and mortality rates plummeted. Unfortunately, intubation and mechanical ventilation are highly invasive, and some babies suffered significant complications.

A group of obstetricians and neonatologists at American Fork Hospital argued that since borderline preemies have lungs that are almost mature, a milder intervention, "nasal continuous positive airway pressure," which involves blowing pressurized air through the newborn's nose, might work. In a clinical trial, intubation rates fell from 78% to 18%. The children stayed in the nursery, not the far more expensive newborn ICU. With the simpler, less invasive care, the hospital's total operating costs for these children fell by $544,000 a year. But fee-for-service insurance payments dropped by $873,000, causing a $329,000 dip in the hospital's operating income. The hospital also had to bear the costs of developing and implementing the change. Moreover, when Intermountain decided to deploy the new methods across all its hospitals—clearly the right thing to do for the children—that $329,000 turned into more than $5 million in annual losses.

> When Intermountain rolled out a better, less invasive lung treatment for premature babies—clearly the right thing to do—it lost $5 million in income.

These examples raise critical questions: Should care delivery groups invest in quality improvements that reduce costs if it could mean their own financial demise? Even if a group does so because it's the right thing for patients, where will it find the resources to launch its next waste reduction project? Shouldn't the windfall that health insurers receive from waste reduction help fund further improvements? If sharing in the savings strengthened the care delivery group financially, wouldn't it become a more effective competitor, encouraging other groups to adopt the same cost-saving strategies?

We believe that population-based payment addresses these issues, because it encourages providers to attack all waste, by ensuring that they benefit from the savings. Because per case systems, including the new bundled payment approaches, don't offer the right financial incentives, close to half of all waste reduction opportunities are likely to go unrealized under them. Under fee for service, the situation is even worse: More than 90% of such opportunities will probably fall by the wayside. (See the exhibit "Who Gets the Savings from Waste Reduction?") Population-based payment has other advantages as well:

Higher returns. For care delivery groups, waste elimination under PBP has a far more positive financial impact than revenue enhancements do under pay-for-volume systems. Only 5% to 9% of all new revenues from a successful, well-managed new fee-for-service or per case service will find their way to a care delivery organization's bottom line. From 50% to 100% of the savings generated through waste elimination in a PBP system will.

A bigger opportunity for more providers. The total size of the opportunity—a minimum of $1 trillion a year in the United States—dwarfs any financial gains from offering new services. Any competent care delivery group can immediately act on that opportunity; that's not true with new services. Eliminating waste often requires much smaller investments than launching new services, especially if those services rely on cutting-edge technologies.

Cheaper, higher-quality care for patients. PBP would create a market in which care delivery organizations would compete for patients on the basis of the cost and quality of their clinical services. Competition would prod them to pass some of the savings on to patients and to give them better care.

Judging by what's going on in the market beyond the Medicare initiatives, others seem to agree that the population-based payment model is best. An increasing number of care delivery groups have started their own insurance companies or partnered with existing insurers, and many large health insurers have purchased care delivery groups. Combining care

delivery and insurance in one organization creates a de facto population-based payment system.

Finding the Tipping Point

Most care delivery groups now navigate a complex mix of discounted fee-for-service (commercial insurance) and per case (Medicare, plus some commercial insurance) payment. Population-based payment—capitated payment made directly to care delivery groups—remains relatively rare. Yet if it were adopted more broadly, groups that aggressively cut waste, as Intermountain did, would benefit financially; the revenues they received for treating each patient would hold steady, while their costs would fall. The key is identifying and reaching the tipping point: the proportion of a group's total payment that must come through capitation in order for gains from waste elimination under PBP to outweigh losses under other payment systems.

To explore that question, we built mathematical and empirical models. Under conditions simulating the operations of both community care groups and academic medical centers, the tipping point was consistently below 30%. If 23% to 29% of a group's payments came through PBP, the group improved its finances by concentrating on waste elimination.

Answering the Critics

Opponents of population-based payments raise three main concerns about them—all of which we believe are unfounded.

Objection 1: PBP's financial incentives will cause rationing, leading clinicians to withhold necessary care. Some critics cite the 1990s HMO experience to support that viewpoint. But they are wrong for a number of reasons.

First, the science of assessing clinical quality, while still imperfect, is dramatically better than it was in the 1990s. To a much greater degree than the HMOs of that era, all proposals for pay-for-value, including capitated payment, contain measures to ensure that each patient receives all necessary and beneficial care, at least to the degree achieved by the current fee-for-service and per case payment systems.

Second, the HMO movement placed oversight of care decisions in the hands of an insurance company. That created conflict between patients and their clinicians on one side and a distant, financially driven corporation on the other. Making capitated payments directly to care delivery groups and eliminating the insurers' supervisory role remove the fundamental conflict that doomed the HMO movement.

Finally, there is solid historical evidence that when physicians are asked to take costs into account in treatment decisions, the vast majority consistently do what's clinically best for the patient. During the 1930s and the 1940s, before broadly available third-party payment for health care, physicians routinely considered a family's resources when providing care. During HMOs' heyday, concerns about rationing were fears, not reality: Empirical measurement of quality showed, on average, a slight but significant increase in the quality of care.

The healing professions select for ethical behaviors, train their members deeply in them, and monitor for violations. While failures do occur, they're rare. When they happen, they're corrected. The medical professions' ethical codes of conduct actually work.

Objection 2: Care delivery groups are not best equipped to address problems of fragmented care and to promote population health. Most people agree on the need to better coordinate care delivery in the United States. The current system is deplorably fragmented, forcing patients to navigate a confusing maze of independent primary, specialty, and hospital care. There's also consensus that the country should expand

Who Gets the Savings from Waste Reduction?

With most health care payment methods, much of the savings from waste cuts goes into the pockets of payers (mainly insurers and, to a much lesser degree, employers and patients), not to the care delivery groups behind the quality improvement initiatives. That undermines the groups' finances and ability to invest in further innovations that rein in spending. Population-based payment is the only system that allows groups to benefit from reducing all three categories of waste.

TYPE OF WASTE	% OF ALL WASTE	PAYMENT METHODS			
		COST-PLUS	FEE FOR SERVICE	PER CASE	POPULATION-BASED PAYMENT
PRODUCTION LEVEL INEFFICIENT PRODUCTION OF INDIVIDUAL CARE UNITS, SUCH AS DRUGS, TESTS, NURSING SUPPORT	5%	PAYER	PROVIDER	PROVIDER	PROVIDER
CASE LEVEL USE OF UNNECESSARY OR SUBOPTIMAL SERVICES IN TREATING A CASE	50%	PAYER	PAYER	PROVIDER	PROVIDER
POPULATION LEVEL UNNECESSARY OR AVOIDABLE PATIENT CASES	45%	PAYER	PAYER	PAYER	PROVIDER

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population-wide efforts to promote healthful lifestyles and immunization to prevent diseases, and early detection to nip them in the bud. Some argue that health insurance companies are best positioned to achieve these goals.

We disagree for several reasons. While it's true that coordinated care is essential to reducing waste and increasing quality, it works most effectively and efficiently when embedded within an integrated care delivery organization—a network of providers that have agreed to offer a continuum of care to a defined population and to be accountable for clinical and financial outcomes. Such groups already account for between a third and half of all care delivery in the country, and their share is growing rapidly. Even if an integrated care delivery group doesn't contain every essential service, it's as well positioned as an insurance company to partner with other providers for additional services. Moreover, we estimate that at least one-third of all opportunities to improve population-level health reside exclusively within specialty and hospital-based care delivery—well outside the reach of insurance companies. The new way to treat newborns with immature lungs cited earlier is one of many such examples.

Last, even when insurance companies do have some ability to address population-level waste, care delivery groups are still more effective at it. For example, Intermountain has found that embedding "appropriate use criteria" in clinical practice, where physicians consult with patients to make treatment choices, prevents unnecessary or harmful care better than insurance-based preauthorization does. Intermountain's cardiologists, for instance, routinely employ such formal evidence-based criteria when counseling patients who might need heart catheterization, stents in the arteries that supply blood to the heart, or permanent heart pacemakers and defibrillators. The result is that the use of such treatments has fallen by almost 25% below Intermountain's already low rates, eliminating about $30 million in waste annually. Meanwhile, quality measures showed slight improvements in clinical outcomes.

Objection 3: It would be better to expand bundled payments. The use of bundled payments has focused mostly on clinical conditions with well-defined boundaries, such as cataract eye surgery, total joint replacements, uncomplicated deliveries, and simple outpatient upper respiratory infections. Some propose applying it to more-complex cases, such as the management of chronic diseases like diabetes, heart failure, and asthma. That approach, they argue, would give patients greater choice and make health care markets more competitive. (See "How to Pay for Health Care" on page 88.)

This approach to bundled payments is sometimes called "disease capitation." It's a very small step away from full capitation. It attempts to push actuarial risk analysis down to the individual patient level, rather than analyzing risk for a group of patients. Such analysis is technically difficult. In addition, this approach could create strong incentives for care delivery groups to select patients, conditions, and treatments based on financial returns rather than patient need.

> Population-based payment gives provider groups strong incentives to perform interventions so that their services aren't needed in the first place.

Most people who have chronic diseases such as heart failure, hypertension, asthma, and depression suffer from several at once. This is especially true with elderly patients, whose needs often include palliative care, help with bowel issues, and general pain control. Any care delivery group has to treat the whole person, not just the disease; it must supply comprehensive care for all of a patient's conditions, either by providing it directly or coordinating with other groups. Bundled payment systems, however, spur patients to seek out highly specialized groups that treat only one disease and its related conditions.

Finally, bundled payments don't directly encourage prevention. In contrast, PBP gives care provider groups strong incentives to perform interventions so that their services aren't needed in the first place—something capitated care delivery groups are starting to do under the banner of "population health."

Proof That Population-Based Payment Works

The experience of Intermountain Healthcare, which serves about 2 million people in Utah, Idaho, and surrounding states, shows that a population-based payment model is viable.

Intermountain has its own insurance subsidiary: SelectHealth, the largest commercial health insurer

in the region, which has some 800,000 enrolled members. Through its commercial insurance business, capitated Medicare Advantage programs, and a new capitated Medicaid program introduced by the state of Utah, SelectHealth now pays for more than 30% of all care delivered within the Intermountain system. Add true charitable care, and capitated care accounts for over 35% of Intermountain's business.

As a nonprofit with a social mission, Intermountain regards the patients and communities it serves as its "shareholders." Its leaders and trustees believe that access to care is paramount. In 2011, recognizing that access depends on affordability, Intermountain's CFO set a goal of dropping the group's year-over-year rate increases within 1% of the consumer-price-index inflation rate by the end of 2016.

Intermountain is making good progress toward that goal. (See the exhibit "Waste Cutting That Works.") Through 2015, waste elimination reduced its total cost of operations ("revenues," under traditional fee-for-service-based health care accounting systems) by 13%. But since more than 35% of Intermountain's care is now compensated through capitated payment—well past the tipping point—the group has been able to remain financially strong: With consistently healthy operating margins, it boasts the highest bond ratings in the industry. The cardiac-medication and newborn initiatives, which initially hurt Intermountain's operating income, now make financial contributions. So do a whole host of other waste reduction innovations, such as a new supply-chain management system, the introduction of best-practice standards for high-volume diseases, and primary care clinics that coordinate all aspects of medical and social services.

IF 35% to more than 50% of total health care spending is wasted, then the 13% drop in operating costs that Intermountain has achieved is merely a good start. Large financial opportunities remain.

In 2014, Intermountain, which employs more than 1,350 physicians, launched a new program that allows interested independent physicians to participate in population-health efforts and share in the savings they generate. Under the modified fee-for-service system described earlier, these physicians, along with the employed group, receive significant payment when total costs are reduced, patient satisfaction is increased, and quality measures—which guarantee that no physician is withholding beneficial care—improve. About 1,200 of the more than 4,000 independent physicians that work with Intermountain have signed up.

In the fall of 2015, Intermountain used the savings generated by waste elimination to offer business customers a new insurance product. It limits total rate increases to 4% a year for three years—a level likely to be one-half to one-third of general insurance rate increases in Intermountain's markets. The organization sees this as a "dividend" to its "shareholders"—the patients and communities it serves. In return for low rates, businesses have to participate in disease prevention and activities that promote better health—for example, encouraging their employees to exercise regularly and eat wisely, to stop using tobacco products, to avoid excessive alcohol consumption, and so on.

Deming got it right. Raising quality by reducing process variations and rework can eliminate waste and bring down operating costs. Better products at lower costs generate higher value, which helps organizations achieve better market positions. Strategies based on that thinking have transformed other industries. We believe that they will do the same in health care. Population-based payment will play a critical role in helping care delivery groups make that leap. ▽

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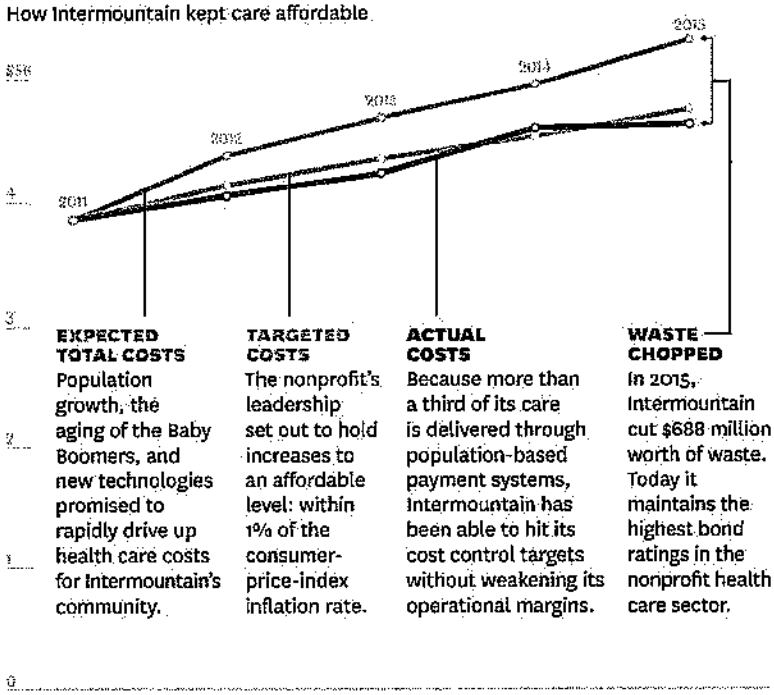
Waste Cutting That Works

How Intermountain kept care affordable



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White House Roundtable Meeting
Anti-Kickback Statute (AKS) and Stark Law Modernization
June 27th, 2019

Speaker	Organization	Topic
Nick Turkal	Advocate Aurora Health	Introduction on Value and Barriers to Care Coordination
Tom Feeley	Harvard Business School	Importance of Value in Health Care
Jorge Lopez, Jr.	Memorial Sloan Kettering Cancer Center	Overview of the Fraud and Abuse Laws (Stark, AKS and Beneficiary Inducement)
Blair Childs	Premier	How the Stark Law Creates Barriers to Value-Based Arrangements
Jeff Bromme	AdventHealth	Changes Needed to Stark Law Regulations
Brian Connell	Leukemia and Lymphoma Society	A Patient Perspective on Reforms to the AKS
Chris White	AdvaMed	Barriers Created by AKS
Saliha Greff	Medtronic	Changes Needed to the AKS Regulations
Mary Grealy	Healthcare Leadership Council	Broad Multi-Stakeholder Support for Stark and AKS Reform
Greg Poulsen	Intermountain Healthcare	Provider Support for Modernization
Kerri Gordon	Allina Health	Provider Support for Modernization
Joyce Rogers	Advocate Aurora Health	Conclusion

White House Roundtable on Fraud and Abuse Modernization

June 27th – 3:00 PM

Biographies of External Participants

Jeff Bromme, General Counsel of Advent Health

Jeffrey Bromme serves as Executive Vice President and Chief Legal Officer at Advent Health, a large non-profit, Florida-based health care system with operations in nine states. He leads the department providing legal services to Advent providers, the advocacy and policy departments, and tax department. He previously served as General Counsel to the U.S. Consumer Product Safety Commission, clerked for the Honorable Will Garwood, U.S. Fifth Circuit Court of Appeals. Bromme earned his JD from the University of Texas School of Law, and a BA from Southwestern Adventist University.

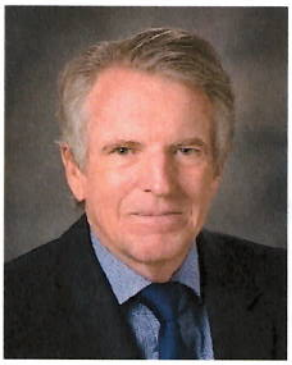
Blair Childs, Senior Vice President of Premier

Blair Childs is considered a national expert in health policy, advocacy, and reform. He currently serves as the Senior Vice President of Public Affairs at Premier, having previously been Executive Vice President of Strategic Planning and Implementation at AdvaMed. Blair has been at the center of health care policy issues in Washington for over two decades, leading reform efforts on the state and national level. He is a graduate of Middlebury College.

Brian Connell, Executive Director of Federal Affairs at Leukemia and Lymphoma Society

Brian Connell is the Executive Director of Federal Affairs for the Leukemia and Lymphoma Society. He has experience leading legislative strategy and coalition-building for non-profits, industry groups, and government. Connell started his career working in Congressional offices, eventually moving on to work as the Director of Government Relations for the Medical Imaging and Technology Alliance. He holds a BA in Political Science from Evansville University.

Tom Feeley, Senior Fellow, Harvard Business School



Thomas Feeley, M.D. is a Senior Fellow at Harvard Business School (HBS) and Professor Emeritus at the University of Texas MD Anderson Cancer Center. At HBS he is involved in research and education of value-based health care in the Institute for Strategy and Competitiveness with Harvard University Professor Michael Porter. At the University of Texas, Feeley was the Helen Shafer Fly Distinguished Professor of Anesthesiology, and headed their programs in anesthesiology and critical care and their Institute for Cancer Care Innovation. Feeley is a prolific author and researcher in health care outcomes, value-based systems, and information technology. His clinical background is in anesthesiology and critical care. Feeley earned his MD and BA at Boston University.

Kerri Gordon, Vice President for Government and External Affairs, Allina

Kerri joined Allina Health in March of 2010. In her role as Vice President of Government and External Relations, Kerri oversees all local, state and federal public policy efforts on behalf of Allina Health. Prior to her work at Allina, Kerri oversaw public affairs for Clearway Minnesota. Previous work included lobbying for a firm in Washington, D.C., and working for the Minnesota Senate. In 2002, Gordon received her Masters in Public Policy from the Hubert H. Humphrey Institute of Public Affairs at the University of Minnesota. Gordon attended American University in Washington, DC where she earned her undergraduate degree.

Mary Grealy, President, Healthcare Leadership Council

Mary Grealy is the President of the Healthcare Leadership Council, a policy advocacy group representing all sectors of the industry. She has led efforts to reform Medicare and improve care quality at several industry groups in her career. She has been ranked multiple times in Modern Healthcare as one of the 100 Most Powerful People in Healthcare and was named in their Top 25 Women in Healthcare in 2009. Grealy holds a JD from Duquesne University School of Law, and a BA from Michigan State University.

Saliha Greff, Vice President and General Counsel, Respiratory, Gastrointestinal and Informatics, Medtronic

Saliha Greff is the VP and General Counsel in the Respiratory, Gastrointestinal, and Informatics division of Medtronic, the world's largest medical device company. She was previously the Chief Compliance Officer for both the Respiratory and Monitoring Solutions and Vascular Solutions businesses at Covidien, which was acquired by Medtronic in 2014. Greff earned a JD from Syracuse University College of Law, an MPH from Harvard, and a BA from University of Michigan.

Jorge Lopez, Jr. Executive Vice President and General Counsel of Memorial Sloan Kettering Cancer Center

Jorge Lopez, Jr. serves as General Counsel at Memorial Sloan Kettering, a world-renowned cancer hospital based in New York City. He has decades of experience advising on health care regulatory issues, industry issues, and policy, particularly related to cancer care. Lopez was previously a longtime partner at Akin Gump Strauss Hauer & Feld, a large international law firm. He earned his JD at Harvard Law School, and a Masters in Economics and BA in Economics from the Catholic University of America.

Gregory Poulsen, Senior Vice President, Intermountain Healthcare

Gregory P. Poulsen, M.B.A., is Senior Vice President for Intermountain Healthcare. As a member of Intermountain's four-member management committee, he shares responsibility for the operational and strategic issues of the organization. Mr. Poulsen has direct responsibility for strategic planning, research and development, marketing, information technology, and e-business at Intermountain, which he joined in 1982. Mr. Poulsen received his bachelor's degrees in physics and biology, and a master's degree in business administration, from Brigham Young University.

Joyce Rogers, Chief Government Affairs Officer, Advocate Aurora Health

Joyce Rogers serves as the Chief Government Affairs Officer at Advocate Aurora Health. Previously, she worked at AARP, serving as a senior vice president of government affairs, where she led federal and state advocacy for the organization, Rogers has worked in government affairs for over 20 years in Washington, preceded by time working in the House of Representatives. Joyce received her JD from the University of Pennsylvania and her BA from Williams College.

Nick Turkal, CEO of Advocate Aurora Health

Nick Turkal is the President and CEO of Advocate Aurora Health, an integrated health care system serving Wisconsin and Illinois. He continues to practice medicine as a family physician while serving in this position. Turkal has been named one of the 100 Most Influential People in Healthcare and one of the 50 Most Influential Physician Executives by Modern Healthcare. Prior to joining Aurora Health Care (now Advocate Aurora), he served as a clinical professor and Dean of University of Wisconsin-Madison's medical school. Turkal received his MD and BA from Creighton University.

Chris White, General Counsel of AdvaMed

Christopher White is the Chief Operating Officer, General Counsel, and Secretary of AdvaMed. White has worked on issues in health care regulatory compliance, fraud, and abuse for over 30 years in Washington. He is a frequent speaker and guest writer on health industry issues. White received his JD from Catholic University Law School, and his BA from Wake Forest University.

Ladd Wiley, Attorney at Law, Olsson Frank

Ladd Wiley is Chair of the Health Industry Policy and Regulatory Practice at OFW Law. He provides counsel to a large range of health care clients, including delivery systems, medical device manufacturers, and biopharmaceutical companies. He has had a long career in both the public and private sectors, from a large international firm to leadership in his home state of Wisconsin. Wiley previously served as Principal Deputy Counsel of the U.S. Department of Health and Human Services in the Bush Administration. He earned his JD from the University of Wisconsin, and a BA from Cornell College of Iowa.