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Regulatory Reform Needed to Foster Population-Scale Genomic Research

Modernization of the regulatory underpinnings of the genomic research infrastructure is needed to enable large-scale data sharing for the next phase of genomic understanding, according to the whitepaper *From Evolution To Revolution: Building the 21st Century Genomic Infrastructure*, released by the Center for Data Innovation and Health IT Now. The report calls for public sector leadership to address barriers to building the population-scale genomic research infrastructure required for President Obama's Precision Medicine Initiative including addressing system-wide interoperability, consent standardization, and privacy issues.

While federal reforms to the regulatory system are needed to improve "the productivity of research," cooperation between the public and private sectors will be needed to create a "functional and broad-based data-sharing model," the organizations say. The paper, the organizations believe, can steer policy-makers addressing practical issues associated with genomic data, including the National Institutes of Health, which is currently developing an implementation plan for the president's Precision Medicine Initiative.

"As the technical limits to genomic research recede, institutional barriers are looming larger," the organizations write in the paper. "Federal and state rules govern ... every facet of the transfer, analysis, and communication of health data. These strictures lock in place paper-era practices and shield medicine from the kind of disruptive, IT-driven innovation that is transforming other sectors of our economy."

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Proposed Medicare Fee Schedule Changes Acknowledge Compliance Realities and Focus on Value

In the wake of the SGR's demise and the rise of alternative payment models, the Centers for Medicare and Medicaid Services' latest proposed revisions to the Medicare fee schedules support those developments. As we reported in June, the repeal of SGR via passage of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) was only the first step and now the hard work of actually effecting the transition to value-based reimbursement begins. (See *National Intelligence Report*, April 29, 2015, p.1)

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Regulatory Reform Needed to Foster Population-Scale Genomic Research, *from page 1*

Turning the genome into actionable medical information is both enormously costly and logistically challenging. Currently, a healthy patient's genome "offers only modest immediate clinical benefit, though the research value can be considerable." Unfortunately, the business case for the private sector to invest in the underlying information technology (IT) systems and upgrades needed to foster genomic medicine, is not "straightforward," the report explains.

Researchers have already identified the low-hanging fruit of the genome—the diseases caused by changes in single genes. Unfortunately, the human genome is more complex than imagined and to make progress in understanding risk of common diseases, such as type-2 diabetes, big data analytics linking the medical records and genome data of a million people is likely required. Undertakings like this are at the core of the federal Precision Medicine Initiative and will require curating large databases and responsibly sharing the data.

Current privacy laws present "formidable obstacles" to realizing the potential of genomic medicine...

To foster an infrastructure capable of these large data needs, the Center for Data Innovation and Health IT Now specifically recommend:

- Federal initiatives to improve interoperability and data sharing—Genomic and other health data must be able to be retrieved and compared across electronic health record (EHR) systems. Some solutions should be top-down, like requiring adoption of interoperability standards through the EHR certification process. These requirements, the authors say, should include standardized vocabulary and data, and standards-driven protocols for sending, receiving, and querying records. Additionally, unique uniform patient identifiers could ease the administrative burden of data sharing. The report also suggests bottom-up solutions, such as giving patients co-ownership of their EHR data (including their sequencing results), would incentivize standard setting and promote data donation choices by patients. Lastly, interoperability is needed to scale research efforts, the authors say, with standardization of consent forms.
- Fostering patient engagement—Giving patients access to their health data is one critical step, but the organizations say public and private sectors need to recognize their shared interest in educating consumers about the transformative role genomics and big-data applications will play in the future of health care.
- Privacy rules need to be more "pliable"—Current privacy laws present "formidable obstacles" to realizing the potential of genomic medicine and reassessment of the costs and benefits of these policies could produce less burdensome models for protecting privacy, the report says.

Note that this is not the first report to call for regulatory action addressing genetic data. In the June issue of *National Intelligence Report*, we highlighted a report authored by researchers explaining post-market data is needed to ensure safety and effectiveness of genetic testing and calling for Congressional action to "incentivize the development of the massive data systems that doctors and regulators will need in order to make these tests safe and effective for patients."

Takeaway: For the Precision Medicine Initiative to be successful, the research infrastructure supporting a better understanding of genomic medicine must be improved in the areas of data sharing, patient engagement, and privacy protection.

Medicare Fund Still Projected to be Solvent Until 2030

While Medicare celebrates its 50th year this month, the Centers for Medicare and Medicaid Services (CMS) announced that the trust fund supporting Medicare hospital insurance coverage is still projected to remain solvent until 2030 and cost growth continues to be low, according to a Medicare Trustees Report. Medicare spending growth per enrollee has been averaging 1.3 per cent during the last five years and is projected to be lower than "overall growth in overall health expenditures" during the next decade, according to a CMS press release announcing the report. "Growth in per-Medicare enrollee costs continues to be historically low even as the economy continues to rebound. While this is good news, we cannot be complacent as the number of Medicare beneficiaries continues to grow," said Acting CMS Administrator Andy Slavitt in the release. "That's why we must continue to transform our health care system into one that delivers better care and spends our dollars in a smarter way for beneficiaries so Medicare can continue to meet the needs of our beneficiaries for the next 50 years and beyond."

The Trustees recorded 2014 Medicare expenditures of $613 billion

Although the SGR system was replaced, the report describes MACRA's provisions as a short term fix and says that, long-term, there will still be payment issues as additional payments and bonuses end in 2025, meaning physicians will again experience a painful payment reduction. It also notes that the MACRA solution doesn't account for economic changes that could occur or increase in physicians' costs: "The Trustees anticipate that physician payment rates under current law will be lower than they would have been under the SGR formula by 2048 and will continue to worsen thereafter." Thus, without future legislative changes "the Trustees expect access to Medicare participating physicians to become a significant issue in the long term under current law."

The Trustees recorded 2014 Medicare expenditures of $613 billion. Additionally, although the report relies on cost-cutting measures in the Affordable Care Act, the Trustees report that current projections still predict "a substantial financial shortfall" in the future unless further legislation is enacted; the Trustees recommend Congress and the Executive branch work together "with a sense of urgency" to effect such legislative action "sooner rather than later."

Takeaway: While there was much rejoicing at the repeal of SGR, the Medicare Trustees caution that it was once again a temporary fix to a payment problem that has by no means gone away. G2

National Health Care Spending Still Growing, But Slower than Expected

While not at an aggressive rate, health care spending is still projected to continue growing according to a Centers for Medicare and Medicaid Services (CMS) Office of the Actuary report published this month in *Health Affairs*. Total health care spending is predicted to grow an average of 5.8 percent per year between 2014-2024—but that is much less than the 9 per cent average growth rate reported for the thirty-year period ending in 2008. "We cannot be complacent," warned Andy Slavitt, acting administrator for CMS, in a press release announcing the report. "The task ahead for all of us is to keep people healthier while spending smarter across all categories of care delivery so that we can sustain these results."

The report predicts that in 2014 health care spending will have reached $3.1 trillion, up 5.5 per cent from the prior year thanks in large part to many gaining coverage for the first time under the Affordable Care Act (ACA). That translates to about $9,695 per person. By 2024, 19.6 percent of the U.S. gross domestic product will be attributed to health care as the number of insured persons is projected to rise to 92.4 percent in the next 11 years.

For Medicaid, while spending overall increased 12 per cent for 2014 largely due to enrollment increasing with coverage expansion under the ACA, spending per person is predicted to fall .8 percent thanks to healthier new enrollees.

More good news: premium growth is also expected to slow down with only a 2.8 percent growth in private health plan premiums for 2015 (and staying below 6 percent through 2024) due to healthier enrollees and employers offering more high deductible plans. Despite these high deductible plans, the report still predicts the portion of spending that comes out of American's pockets will fall to 10 percent in 2024 (from 11.6 percent in 2013).

Takeaway: The Affordable Care Act and Medicaid expanded eligibility have increased the number of insured but overall the rate of growth in health care cost remains slower than historical averages.

Medicare and Medicaid at 50, by the Numbers

The Centers for Medicare and Medicaid Services released some data regarding enrollment the week of Medicare and Medicaid's 50th anniversary. Here are some highlights:

- **55 million:** the number of Americans currently covered by Medicare
- **19.1 million:** the number of Americans covered by Medicare after its launch in 1966
- **3 million:** the number of new Medicare enrollees in the past three years as the Baby Boomer generation reaches Medicare eligibility
- **71.6 million:** the number of Medicaid and Children's Health Insurance Program enrollees as of May 2015
- **39.2 million:** the number of Americans with Medicare Part D coverage through stand-alone prescription drug plans and Medicare Advantage with prescription drug coverage
- **5,601,363:** the number of Medicare and Medicare Advantage enrollees in California, the state with highest enrollment in those programs
- **82,957:** the number of Medicare and Medicare Advantage enrollees in Alaska, the state with the lowest enrollment in those programs

Sources: Centers for Medicare and Medicaid July 28, 2015 press release, "*On its 50th anniversary, more than 55 million Americans covered by Medicare*"

Proposed Medicare Fee Schedule Changes, *Continued from bottom of p.1*

"CMS is building on the important work of Congress to shift the Medicare program toward a system that rewards physicians for providing high quality care," said Andy Slavitt, acting administrator of CMS, in a statement regarding the proposed physician fee schedule update. "Thanks to the recent landmark Medicare and children's health insurance program legislation, CMS and Congress are working together to achieve a better Medicare payment system for physicians and the American people."

Clinical Laboratory Fee Schedule Focuses on Drugs

The July 16 Public Meeting for the new Clinical Laboratory Fee Schedule addressed, most notably, drug testing codes. "We stated our concern about the potential for overpayment when billing for each individual drug test rather than a single code that pays the same amount regardless of the number of drugs that are being tested," CMS said in its explanation that accompanied the codes, referencing its 2015 laboratory fee schedule final determinations. For 2016, it has proposed to delete G-codes G0431, G0434 and G6030 through G6058 and create two G-Codes for drug screens (any number of drugs/classes) per day, and drug tests (any number of drugs/classes) per day. CMS indicated final determinations will be issued this fall.

Physician Fee Schedule Seeks Public Comment

The Proposed CY 2016 Physician Fee Schedule Rule was published July 15 in the Federal Register and CMS seeks public comment in the 60-day comment period, on many issues, including the following:

- MIPS, the merit-based incentive payment system included in MACRA, including the appropriate low-volume threshold to be used to exclude eligible professionals from MIPS.
- A proposal to provide separate Medicare payment for advance care planning services.
- Implementation of alternative payment models under MACRA and incentive payments for eligible professionals participating in alternative payment models. CMS indicates it will publish questions on this issue for public comment through a future Request for Information.
- Information regarding typical batch size and block size for pathology services and "approaches to obtaining accurate information that can facilitate our establishing payment rates that best reflect the relative resources involved in furnishing the typical service, for both pathology services in particular and more broadly for services across the PFS." CMS indicates that "given the high volume of many pathology services" it is concerned about accuracy of block number assumptions which affect the PE RVUs for PFS services.
- Issues raised by potential expansion of the Comprehensive Primary Care Initiative which promotes coordination of care for Medicare beneficiaries. The initiative is currently implemented in seven regions using a payment model involving "non-visit based per beneficiary per month care management payments and shared savings opportunities." Note this request for information is for planning purposes and CMS emphasized that it isn't proposing an expansion at this time.
- Stark Self-Referral prohibitions and their impact on alternative payment methods—see the next page for further discussion of self-referral issues.

A fact sheet and link to the final rule can be found on CMS website.

Self-referral discussion recognizes complexity

Noting the Affordable Care Act established a requirement for a self-referral disclosure protocol allowing providers to self-disclose "actual or potential violations of the physician self-referral law," CMS indicated the goal of the proposed fee schedule update was to "accommodate delivery and payment system reform, to reduce burden, and to facilitate compliance." CMS said it had learned from self-disclosures and other inquiries "that additional clarification of certain provisions of the physician self-referral law would be helpful." It also intends to "expand access to needed health care services" so proposes two exceptions and clarifies other provisions.

CMS proposes new provisions allowing hospitals (and FQHCs and RHCs) to assist physicians in employing nonphysician practitioners.

Here are some highlights of the proposals concerning the self-referral law.

Physician recruitment and retention. CMS proposes new provisions allowing hospitals (and FQHCs and RHCs) to assist physicians in employing nonphysician practitioners. CMS cites the increase in number of insureds, the growing aged population, "alarming trends in the primary care workforce shortage projections," and changes in health care delivery and payment as reasons supporting this change. CMS also proposes revisions to the definition of geographic areas served by FQHCs and RHCs for purposes of recruitment of physicians to those areas. Finally, CMS suggests changing language in compensation exceptions to make sure the phrase "taking into account" referrals is consistently used rather than other phrases such as "based on" referrals.

Requirement for written agreements. CMS notes that the self-disclosure protocol has yielded "numerous submissions" regarding requirements for written agreements—specifically failure to have a written agreement, failure to get signatures, and failure to renew expiring agreements. Apparently the self-disclosures reveal confusion about the writing requirements for leasing and other compensation exceptions, including whether the writing must be in one document or contract. While it says one written document is "the surest and most straightforward means of establishing compliance" with the exceptions, CMS says there is no requirement that all terms of an arrangement be in one formal contract. Instead a collection of documents including "contemporaneous documents evidencing the course of conduct" can meet the requirements. Finally, it proposes revising holdover provisions to allow indefinite holdovers if certain safeguards are met.

Definition of remuneration. CMS has also proposed clarifications on some definitions such as remuneration. In one exception, the self-referral regulations exclude from the definition of remuneration any items, devices or supplies "used solely" to collect, transport, process or store specimens for the entity providing those items or to order or communicate test results. But CMS was concerned that "used solely" was being misinterpreted to mean that if an item, device or supply could not be used for two or more of six purposes named in the statute without being deemed a compensation arrangement. So it proposes clarification that the item must be used for the purposes listed in the statute—so an item need not be used for only one purpose; it simply must only be used for the purposes stated in the statute. Potential violations will arise if the item, device or supply is used for purposes other than those listed in the statute.

CMS also addressed a 3rd circuit court of appeal interpretation of remuneration, which held that when a physician uses hospital resources such as exam rooms or supplies or nursing staff while treating hospital patients, that use of resources constitutes remuneration even if the hospital bills for its resources and the physician separately bills for his services. CMS didn't propose any regulatory changes but explained that such arrangement wasn't remuneration as long as the physician and hospital don't provide benefits to one another and separately bill. But if one party billed globally for both physician services and hospital resources then a benefit is conferred on the party billing globally.

CMS expressed concern that outside of the Medicare Shared Savings program waivers and Center for Medicare and Medicaid Innovation models, the integration needed for the reform underway would be prohibited by self referral laws.

Timeshare arrangements. CMS created a new exception for timeshare arrangements, described as arrangements in which one entity provides a license to another provider to use its office space and staff and resources but doesn't transfer dominion and control as would occur in a lease. CMS recognized such time share arrangements don't fit within the lease exceptions but said it believes such arrangements can be structured so they don't pose a risk of abuse. So it proposed a new exception for time share arrangements requiring they be in writing and specify the items and resources covered in the arrangement. Such arrangements cannot involve clinical or pathology laboratory equipment other than equipment used to perform CLIA-waived laboratory tests. Instead they must be between a hospital or physician organization and a physician licensee and relate to resources predominantly used to provide evaluation and management services to the licensee's patients.

Alternative payment models. Citing the "significant changes in the delivery of health care services and the payment for such services" since the self-referral law was enacted, the rise of ACOs, the Medicare Shared Savings Program, innovative payment and service delivery models, and the overall shift to value-based reimbursement, CMS solicits comments about how the self-referral law impacts these reforms. Specifically, CMS noted that the self-referral law "by design, separates entities furnishing DHS from the physicians who refer Medicare patients to them." However, the new shift to value-based reimbursement is "premised on the close integration of a variety of different health care providers in order to achieve the goals of improving the experience of care, improving the health of populations, and reducing per capita costs of health care, often referred to as the 'three-part aim.'" CMS expressed concern that outside of the Medicare Shared Savings program waivers and Center for Medicare and Medicaid Innovation models, the integration needed for the reform underway would be prohibited by self referral laws. Thus, CMS seeks public comment "regarding the impact of the physician self-referral law on health care delivery and payment reform." Specifically, CMS wants to hear about barriers to integration as well as need for guidance regarding self-referral law applicability to compensation arrangements that are not part of alternative payment models. To generate conversation, CMS posed 10 questions: including whether new exceptions are needed or which existing exceptions could be expanded to accommodate alternative payment models, and "what aspects of alternative payment models are particularly vulnerable to fraudulent activity."

Takeaway: The journey to value-based health care delivery and payment methods is about to get fully underway and could potentially cause significant change to the way the government seeks to prevent abusive arrangements under the self-referral law. G2

Payment Reform Efforts to Support Cancer Care Coordination

The American Society of Clinical Oncology (ASCO) is proposing to profoundly reform payment for cancer care. ASCO's Patient-Centered Oncology Payment: Payment Reform to Support Higher Quality, More Affordable Cancer Care (PCOP) proposal marks a significant step towards value-based reimbursement, fundamentally restructuring the way oncologists are paid for cancer care. The group believes improved quality and reduced spending are possible by providing "sufficient payment" to support a range of typically unreimbursed services, including payment for care coordination and treatment planning based upon appropriate testing. Furthermore, PCOP would meet the criteria of an Alternative Payment Model as defined in legislation Congress enacted in an effort to repeal Medicare's Sustainable Growth Rate formula.

Central to ASCO's proposal is addressing inadequate payment or currently uncompensated time for services critical to managing a complex illness. As part of the basic PCOP model, the workgroup says oncology practices commit to delivering evidence-based care—ensuring patients receive the most appropriate tests and treatments, while avoiding unnecessary expenses. In return, oncology practices receive four supplemental, non-visit-based payments to support diagnosis, treatment planning, and care management. These monthly payments risk reduction if practices fail to adhere to evidence-based guidelines. Services like Evaluation & Management, infusions of chemotherapy, and drug administration in the practice setting will remain billable under the Medicare Physician Fee Schedule. However, for financially more aggressive practices, additional consolidated and bundled payment models are proposed.

ASCO's PCOP expands upon a previous draft payment reform model the group circulated last year and experts say, takes payment reform even one step further than the Centers for Medicare & Medicaid Services' (CMS) Oncology Care Model (OCM). OCM, a multipayer payment and care delivery model, was unveiled by CMS earlier in the year, but was criticized for keeping fee-for-service (FFS) payments in place.

OCM is based on the oncology medical home concept. Like PCOP, OCM would pay oncologists in part on a per-member, per-month basis, with overall payments tied to financial accountability or risk, as well as quality. Participating practices would receive a $160 per-beneficiary payment on top of Medicare FFS payments for a 6-month episode of care. Additional semi-annual performance-based payments would be made for meeting a set of quality measures.The second part of the plan involves shared-savings payments based on benchmark spending targets. The oncology practice can share in the savings achieved, if they reduce costs more than 4 percent below the target price.

Takeaway: ASCO adds its proposals for changing payment for costly oncology services to the increasing number of groups proposing reforms to accommodate the shift to value-based payment systems.

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