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Diabetes Technology, Innovation, and the U.S. Health Insurance System

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Abstract

The flow of funds in the U.S. health care system is crucial both for the provision of services to patients and to encourage innovation that enables long-term improvement of health services. Rising concern about health care costs often includes concerns about inappropriate adoption of costly or unnecessary technology. Many innovations in diabetes technology may involve personal technology, which does not qualify under existing health insurance categories such as "durable medical equipment" or under a currently defined telehealth technology. In such cases, the diabetes technology industry may be developing types of technology that are so innovative they do not have clearly established payment mechanisms in the existing U.S. fee for service health care reimbursement system. This article describes key features of the U.S. health care payment system relevant to developers of new diabetes technologies.

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Introduction

Journal of Diabetes Science and Technology provides an international forum for the presentation of new biomedical technology and its clinical benefits. Diabetes care is a major target of innovative and international research investments that aim to provide both incremental and transformative changes in how this disorder is managed. Prior articles have focused on the promise of digital technologies[1] and on the challenges faced by innovators and providers of particular categories of new technology due to the reimbursement systems in the United States[2,3] and in Europe.[4] This article provides an overview of the U.S. health care system with respect to diabetes technology and innovation to help innovators understand how their products and services may be received both in the older, code-based fee-for-service system and in newer health care delivery models.

National concern about health care costs has reached unprecedented levels in the United States,[5] enough to spur the first major national legislation for health care reform since the passage of Medicare in the 1960s—passage of the Affordable Care Act in 2010.[6] While health care reform should reduce the number of uninsured Americans, the U.S. health care delivery system as a whole will still remain a complex conglomerate of different types of financing and delivery systems for the foreseeable future. Details of how the traditional fee-for-service payment and claims processing systems function for particular types of technologies[2,3] will change gradually enough that it is still valid to present the Medicare fee-for-service reimbursement framework as a prototype of U.S. health care administration.

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Abbreviations: (CMS) Centers for Medicare and Medicaid, (DME) durable medical equipment, (HCPCS) Healthcare Common Procedure Coding System

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This article describes that traditional, fee-for-service approach in part but also emphasizes that the U.S. health care system is in a state of flux and evolution with new reimbursement and delivery systems emerging alongside the legacy ones. The Medicare and Medicaid programs are administered under one federal agency called the Centers for Medicare and Medicaid (CMS).

Parallel Health Care Systems in the United States

The U.S. health care delivery system contains many different financing and health care delivery models and should not be viewed as a universal fee-for-service-based system. At one end of the spectrum, the United States already has some fairly large and highly integrated systems where there is an integration of health care system ownership, operational management, and financial responsibility. These integrated systems can be as different as the governmental Veteran's Administration health care system[7] and the Kaiser Permanente integrated health care system, which is financed largely by employers who enroll their employees and, often, their family members. However, these two systems have some key similarities, which include a relatively cohesive management hierarchy that receives the funds, owns the system, and is responsible for both capital investments and operational choices in the delivery of health care. In contrast, the federal Medicare program and both nonprofit and for-profit nongovernmental insurance plans own no hospitals and, as a result, transfer largely fee-for-service payments to privately (or less commonly, municipally) owned hospitals and to physician groups. These hospitals and physician groups usually care for patients under many different health insurance plans. When these are traditional fee-for-service plans, both the Medicare program and many commercial insurers depend on detailed coding systems with literally thousands of codes, comprehensive pricing tables for each code, and elaborate claims processing rules to support service- and item-based payments based on claims submitted by the hospitals, physicians, and other types of provider such as durable medical equipment (DME) suppliers or pharmacies.

This fee-for-service model may contribute to poorly coordinated care and excess utilization because it is too difficult for the payor to administratively control all the health care for which claims are submitted, across millions of patients and service episodes. This has led to the development of approaches to manage the care that the payor will pay for, even though the payor does not own the hospitals or employ the physicians. The maximum shift of risk for each patient's costs from the payor to the provider occurs in "capitated care." In this model, the payor contracts with hospitals and physicians to provide capitated care for a fixed annual sum, switching the risk for additional expenditures and services from the payor to the provider. Parts of the Medicare and Medicaid populations and some commercial insurer programs use this approach. In capitated health care, the primary funder (such as Medicare or Medicaid) transfers a *per annum* payment for a beneficiary's health care to an intermediary. The recipient of the Medicare annual capitated payments may be an integrated hospital–physician network such as Kaiser or may be an insurer who receives Medicare funding and then in turn contracts with freestanding hospital and physician systems. The capitated managed care approach accounts for over 20% of Medicare patients and a substantially larger and growing proportion of Medicaid patients. The proportion of patients in capitated commercial plans has variably risen and fallen since the 1980s.[8]

Without jumping to fully integrated or capitated systems, which may place unacceptable levels of cost risk on providers, federal and commercial health care policymakers are seeking to reduce unnecessary expenditures by (a) bundling episodes of care or by (b) providing annualized incentives to reduce total expenditures for individual services that continue to be billed to the insurer.[8] Medicare has provided bundled payment for inpatient hospital admissions for several decades, commonly referred to as the "diagnosis-related group" system. An inpatient hospital admission for an abdominal surgery, a heart attack, or a diabetic coma is given a numeric code, which is cross walked to one of only a few hundred diagnosis-related group codes, and a fixed payment is automatically transferred to the hospital to provide its reimbursement. In the summer of 2013, Medicare proposed more bundling for care in the hospital outpatient setting, for example, by proposing to bundle the individual payments that previously existed for both imaging services and pathology tests to a primary outpatient procedure, and no longer providing line-item payments for these "ancillary" services.[9] This proposes to transfer risk for imaging and pathology costs to the hospital, which, under the proposal, would receive one bundled payment for a health care event such as an outpatient surgery. Both the Medicare system and commercial payers are also experimenting with "accountable care systems," in which

payment is made on a fee-for-service basis through the calendar year and bonuses or penalties are assessed based on total year expenditures.[8]

The Underestimated Role of "Benefit Category"

The original Medicare system, which still has many parallels with U.S. commercial insurance plans, is based on an elaborate set of legally defined "benefit categories" and exclusions. Benefit categories are generally defined very broadly, such as "inpatient hospital services," "outpatient hospital services," "diagnostic tests," "physician services," "ambulance services," and so on. Due to the lengthy legislative history of the Medicare program, some additional benefits are defined very granularly (such as annual mammography), and certain seemingly minor items are carefully enumerated for exclusion from Medicare coverage, such as eyeglasses and hearing aids.

Prior articles in this journal have discussed the legacy fee-for-service payment system for continuous glucose monitors[2] and for conventional glucose strips and blood glucose meters.[3] Lile[3] also describes the sometimes highly burdensome administrative reviews to assess whether strips have been distributed accurately and if not, to recoup funds.

Less-commonly discussed is the fact that benefit categories may have a substantial impact on whether a particular innovative new technology is viewed as eligible for payment at all, without entertaining consideration of its added value in the delivery and management of care for the patient. Medicare requires DME to meet all of several legal criteria.[10] The equipment must be durable, with an expected life of at least 3 years and a replacement not normally before 5 years. It must be primarily for medical use (for example, air conditioners, air filters, and exercise equipment are excluded), and it must be primarily for use in the home (for example, a magnetic resonance imaging scanner is durable for 5 years and is only for medical use but is not primarily used in the home, which is why it is not DME). These rules are a half-century old and were intended for historical durable equipment, such as wheelchairs or home-use hospital-type beds. The rules have also led to some unexpected results that were probably unintended. For example, a home-use drug is not routinely paid for by the traditional Medicare system, yet remarkably, when a $20,000 medication is pumped through a $500 DME pump, the drug is legally construed as "incidental" to the use of a piece of DME, or viewed as a mere supply that allows the DME pump to function with its intended purpose so that payment for the medication is covered in conjunction with the DME benefit. Regarding innovative diabetes technologies, these rules may be adverse to some light modern electronic devices, which are not designed to have a replacement cycle as long as 5 years. Given that they are neither a hospital service nor a physician service nor a drug nor a piece of DME, there is simply no benefit category at present that allows such devices to be payable.

Modern electronic equipment and telehealth equipment generally fits poorly in the DME benefit category, which was designed for classic equipment such as wheelchairs. Payment for downloadable smartphone software, attachments, and remote services that are not traditional "hospital" or "physician" services also may fall into gaps between historical benefit categories. The promising-sounding "telehealth" benefit category under Medicare is defined primarily for services that are closely analogous to a traditional office physician visit but where the patient is at a remote location.

The Underestimated Role of "Coding"

To the extent that a fee-for-service system so far remains a model for much of the U.S. health care market, the codes that convey services delivered are very important. United States law requires that hospital, physician, and equipment and supplies all be communicated by standard codes on standard claims when invoiced to federal or commercial insurers. The code family for equipment and supplies is called the Healthcare Common Procedure Coding System (HCPCS) code set.[11] It is managed by CMS federal employees, who accept formal applications for new codes each January and determine whether a new code is needed in a year-long process with public comment allowed.[12] While a code may be created that is not paid by an insurer, the lack of any code that describes a product makes electronic transactions for reimbursement of that product very difficult.

If a new device or service does not fit an existing Medicare benefit category, it is possible, but historically challenging, to get a new code, even though the HCPCS system applies to all U.S. insurers and not just the CMS federal program.

The rules[12] permit an innovative new device to be ruled ineligible for a new code if it can be described (perhaps imaginatively) by an old code. In this case, the policy response to the application for a new code could be a statement that the product can be described by an existing code. For example, imagine a new adhesive compact replaceable insulin pump/glucose meter combination with a 1-month product life. Such a device may face hurdles getting a U.S. HCPCS code because it is not DME or because it might be represented as a "glucose meter, home use" (which is already classified under a code and a price, even though the old code is only partially representative of the feature set of the innovative new product), or because the new device is not yet the standard of care in the marketplace. While this example may seem extreme and is illustrative, in general, there is an administrative tendency with each year's applications for new codes to categorize a particular new and more expensive technology into an older, less expensive code when administratively possible, absent a compelling reason not to do so. This does avoid gratuitous price inflation for devices that merely have minor features or new model numbers, but only at the risk of deterring investment in true innovation.

Most Recent Policy Trends Are Based on Unit Price

The Medicare agency, to date, does not "negotiate" price but rather sets price by one or another code of laws or regulations, depending on the service in question. For DME, prices are generally set by historic prices dating back to the 1980s, with limited inflation adjustments. New products may be set at the agency's interpretation of a likely current market price, deflated through an administrative calculation to a lower value as if the product had been introduced in the 1980s. This results in fee schedules that generally lag inflation on a current-dollar basis. Nonetheless, there may be cases where market prices may fall substantially below the fixed fee schedule price. Historically, the agency had only an extremely cumbersome federal policymaking method of adjusting prices downward (for example, a downward adjustment of home glucose meter prices in the 1990s involved years of agency effort).[13]

Recognizing that the Medicare agency had limited ability to negotiate or reset DME prices, Congress created a national competitive bidding system, which has already been used in some pilot metropolitan areas for certain products. This program has been started, delayed, altered, and relaunched for several years as of this writing (2013), but the bottom line is that competitively bid prices for some of these products dropped substantially, yielding savings for the government and taxpayers. The larger problem for an area with potentially rapidly evolving and improving new technology is that the bidding process is entirely based on fixed historical codes for older-generation product categories and subcategories, and the allowable brands and model numbers under a particular HCPCS code are fixed and listed by a separate administrative division called the DME Pricing, Data Analysis, Coding Contractor. There is no way to fast-track a truly innovative product into a marketplace that is controlled and regulated in this way. This lengthens the timeline for market penetration and may make the payback period for a risky and innovative new technology unfavorable.

Toward an Innovation-Friendly System: Outlook

Better technology and more efficient, effective health care delivery is imperative for saving costs in health care, as described convincingly by Gottlieb and Makower[14] and Klonoff.[1] But today's administrative health care systems are a legacy of the 1960s. While the claims processing logistics may have changed from IBM punch cards to electronic transmittals over the decades, the basic framework of fixed codes, standardized claims, and frozen price schedules is the same. The two worlds of (a) health care administration and (b) biomedical engineering are as different from one another as the two worlds of science and the arts described by C.P. Snow in the 1950s.[14] The investors, marketers, and technologic and engineering innovators who are creating new generations of diabetes technologies are unlikely to take jobs in health care administration, while the health care bureaucrat is unlikely to have a very rich understanding of the world of Silicon Valley, Route 128, Tel Aviv, and other centers of biomedical innovation.

Effective technology can advance rapidly in an open and competitive marketplace, with informed buyers making the best decisions for themselves, as we have seen in the worlds of smartphones, computers, and other electronic equipment. In health care, of course, a preliminary rate-limiting step is the regulatory process for premarket approval, efficacy, and safety. After regulatory approval, in many cases, it is likely that diabetes patients and their physicians

have a very good idea of how important new advances can be, such as having ready smartphone-based access to your 24 h glucose levels. Right now, it seems that new technologies may come faster than the old health care system can adapt, and it is hard to estimate how severely the health care system's current barriers to small, handheld, or body-worn technologic advances (which are so important in diabetes technology) could be deterring potential investors.

Innovators should know enough about the barriers to innovation to be able to complain articulately.[15] Because the old world of fee-for-service codes may be too fossilized to change quickly, we should look to the new worlds of integrated health care systems and long-term rewards and incentives for providers to facilitate the acceptance and adoption of new technologies. This is where the future lies, and the better new technologies penetrate into accountable care systems and integrated systems, the more pressure there will be for the parallel older systems to accept the new technology as well. But accordingly, the integrated health care system that leaves behind the fee-for-service codes raises a new challenge for innovators: the new technology must be convincing enough, and have enough data, that patients and providers in the more innovative integrated systems want and adopt it. This shift to evidence-based medicine and pharmacoeconomic value, no longer tied so tightly to the codes and legal benefit categories described herein, brings a more rational challenge to the biomedical device industry. That challenge will come from the still-prudent (but more flexible) health care decision makers in these more open parts of the health care market.

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