ket anyway — insurers come and go all the time — but those who do leave now will undoubtedly blame health care reform, including the loss-ratio provisions.

The American Medical Association actively lobbied the NAIC for strong loss-ratio requirements to ensure that insurance premiums actually pay for health care services. The share of premiums that goes to overhead and profit will also become more visible to consumers. Congress concluded that the benefits of transparency and greater efficiency were worth the risk of losing inefficient insurers in some markets. Time will tell whether this judgment was correct.

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Four-Dollar Generics — Increased Accessibility, Impaired Quality Assurance

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The affordability of prescription medications is one of the most pressing public health issues in the United States. Many patients take less than their prescribed doses to make medications last longer or do not fill prescriptions at all because of cost.[1] Both patients without insurance coverage for drugs and those with such coverage underuse medications because of cost[2] — and this problem has grown as employers have cut back on drug benefits. The failure to provide essential medications for chronic diseases may have massive adverse consequences for public health and the overall costs of health care. As we prepare to expand health care coverage while also attempting to manage costs, the problem of affordability of prescription medication will only intensify.

Many have advocated shifting to lower-cost generic medications to improve affordability, reduce health care spending, and promote adherence to drug regimens.[3] Many pharmacy chains have introduced "$4 generic drug" programs, permitting patients to purchase selected generic medications for approximately $4 per month. The prices offered by these programs are substantially lower than the cash prices that people without prescription drug coverage normally pay. Even for those with coverage, paying out of pocket may save money, since the average copayment for generic medications under commercial insurance plans is $10 per month.[4] These $4 programs represent a substantial departure from the usual mechanisms of drug acquisition. Lower medication costs should have desirable effects on medication use, especially as the patents on more therapies for chronic conditions expire, and these low-cost programs have been a welcome advance for low-income patients. An unfortunate side effect, however, has been new problems in health system monitoring and quality assurance.

The first low-cost–generic program, introduced in September 2006 by Walmart and shortly thereafter by Target, offered a limited number of generic drugs at a cost of $4 for a month's supply of each drug. The number of such programs has since increased substantially. Eight of the 10 largest retail pharmacy chains have programs offering low-cost generics.[5] Prices range from $4 to $9.99 per month, or from $10 to $12 for a 3-month supply. Some pharmacy chains charge membership fees for access to these low-cost products. Large pharmacies can afford to offer such low prices because of their purchasing power and the very low production cost of generic drugs. Thus, in addition to increasing the affordability of essential medications for patients with chronic conditions, $4-generic programs are potentially profitable for retailers. They may also

Medications Most Frequently Prescribed in the United States for Chronic Conditions and Their Availability through Low-Cost–Generic Programs at Large Chain Pharmacies.*

Medication	No. of Prescriptions in the U.S. in 2009 (millions)	Available as a Generic?	Available through a Low-Cost–Generic Program?
Simvastatin	83.0	Yes	No
Lisinopril	81.3	Yes	Yes
Levothyroxine	66.0	Yes	Yes
Metformin	52.0	Yes	Yes
Atorvastatin	51.5	No	No
Amlodipine	50.9	Yes	No
Hydrochlorothiazide	47.1	Yes	Yes
Omeprazole	45.4	Yes	No
Furosemide	42.8	Yes	Yes
Metoprolol	40.5	Yes	Yes
Atenolol	38.6	Yes	Yes

* Data on the frequency of prescriptions are from IMS Health; information on availability through a low-cost–generic program is from Walgreens, Walmart, and Target.

draw in customers and expand opportunities to sell other, more profitable products.

The majority of the most widely used generic medications in the United States, including treatments for coronary artery disease, hypertension, and diabetes (see table), may be purchased through these programs. As generic formulations of other blockbuster drugs — including the two most widely sold drugs in the world, atorvastatin (Lipitor) and clopidogrel (Plavix) — become available over the next several years, the role of $4 generics will almost certainly grow, with an expanding effect on the public's health.

When patients purchase medications using prescription-drug insurance, each transaction generates a record of a claim, submitted by the pharmacy to a pharmacy benefit manager, indicating whether the medication is covered, how much the insurer will "allow" for the claim, and what proportion of the allowed amount the patient must pay in copayments, coinsurance, and deductibles. Included with this administrative information are other details that are clinically useful, including the name and dose of the medication and the quantity supplied.

Pharmacy claims data are used increasingly to improve the effectiveness of pharmaceutical care in large populations. Insurers use pharmacy claims to generate performance scores that employers and patients use when making insurance purchasing decisions. The Pharmacy Quality Alliance has developed quality metrics that use pharmacy claims to measure patients' adherence to long-term therapy, and these data may be used to support and target interventions to improve adherence. Researchers use pharmacy claims to evaluate the comparative effectiveness and safety of medications and to determine the real-world consequences of clinical trial results. Pharmacy benefit managers use pharmacy claims to track trends in utilization and expenditure. Pay-for-performance contracts with physicians and hospitals are also partially based on pharmacy claims. All these uses can contribute to long-term improvements in the health care system and may thereby directly benefit both current and future patients.

Unintentionally, the pharmacy chains responsible for the proliferation of $4 generics are undermining the ability to use pharmacy claims for these purposes. Many pharmacies do not submit claims to insurers when patients pay cash, since they have no incentive to do so. As a result, some insured patients who have filled prescriptions with $4 medications will be misclassified as nonusers of or "nonadherers" to these treatments. Because drugs are the most widely used medical interventions and are a cornerstone of the management of most chronic diseases, the consequences of these missing claims are not insignificant. Furthermore, with prescription-drug coverage becoming nearly universal under the Patient Protection and Affordable Care Act, the need to monitor the performance of health systems is even more pressing.

It is ironic that by increasing access to effective medications, low-cost–generic programs may challenge the effective promotion of higher quality in the health care system. Fortunately, when low-cost generics are provided to patients, prescriptions must still be written and patients must

still interact with pharmacies. These steps offer the possibility of reconciling the priorities of affordability and quality assurance.

The simplest strategy is to ensure that pharmacists submit to pharmacy benefit managers all claims for beneficiaries, including those for drugs that are paid for in cash, thereby exploiting the current system of information flow. However, pharmacists will need incentives to submit such documentation, and these incentives must not violate conflict-of-interest and kickback regulations, given the established relationships between pharmacy benefit managers and pharmaceutical manufacturers.

Alternatively, new information systems could be developed. All major pharmacy chains use electronic systems to record transactions and monitor their inventory. These systems contain records of all medication purchases, including those paid for in cash, and could be used to evaluate the quality of prescribing practices. With the increasing prevalence of electronic prescribing, new strategies may be considered for harnessing data on prescriptions written instead of prescriptions filled. Electronic health records, especially those that can be integrated with data from pharmacy and insurance claims, may be another rich data source, once they have proliferated sufficiently to provide representative data. Existing companies, such as Surescripts, have created national networks to aggregate electronic prescriptions with pharmacy transactions and insurer drug claims. Though these processes are primarily used to facilitate electronic prescribing and provide clinical data at the point of care, they could easily be applied to health system monitoring. Furthermore, because insurers and third-party payers share in the expense of such information systems, their cost need not threaten pharmacies' ability to provide $4 generics. Of course, obstacles related to the cost of maintaining these data, privacy concerns, and incentives for data sharing will need to be overcome.

Administrative data have become central to the evaluation and management of the quality of health systems. Although $4 generics have improved access to medications, the challenges created by their advent are not trivial and require innovative solutions. As we strive to control costs for patients and the health care system, we must be certain not to diminish our ability to measure and improve the quality of U.S. health care.

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