


tion are likely to reduce the market penetration of interchangeable biologics.

The challenges to achieving savings from follow-on biologics are large but not insurmountable. First, market-entry hurdles should be low enough to ensure that enough companies compete to affect prices. Public investment in technological advances that can support biosimilar development, such as advancing knowledge about glycosylating human proteins in yeast, can aid all

 An audio interview with Dr. Kesselheim is available at NEJM.org

manufacturers. The FDA can help by promulgating product-specific guidance on how companies can demonstrate biosimilarity or interchangeability, to reduce the disadvantages for the first companies to try. Legislators may also need to reexamine the process for exchanging information about potentially infringing patents, to ensure that innovator manufacturers cannot unreasonably delay the process in order to extend their market exclusivity, and to prevent biosimilar manufacturers from entering into anticompetitive settlements. Such settle-

ments have bedeviled the generic small-molecule drug industry but, since 2003, have had to be reported to the Federal Trade Commission for evaluation of their anticompetitive effects. This requirement may have to be extended to biologic drugs.

Innovative approaches will be required to ensure mandatory, rigorous postapproval research on the safety and effectiveness of biosimilars compared with their innovator predecessors in order to promote confidence in these new products. Over the long term, attention to both these areas will help ensure that U.S. patients benefit from appropriate price reductions for older biologic drugs that are essential for their clinical care. At the same time, fair but appropriately limited periods of exclusivity will reward the innovators of the original products while also spurring them to create new products rather than prolong exclusivity rights over older ones long after such monopolies should have come to a natural end.

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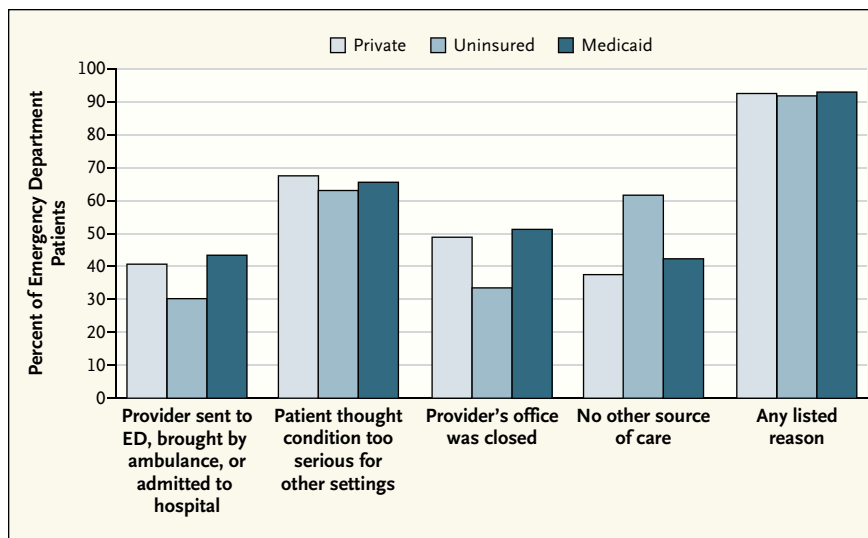
## No Place to Call Home — Policies to Reduce ED Use in Medicaid

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One goal of Medicaid expansion under the Affordable Care Act (ACA) is to provide low-income, medically vulnerable adults with a source of care outside the emergency department (ED) and the means to pay for

that care. Yet Medicaid expansion alone may not reduce ED use among new enrollees. Although some research suggests that Medicaid coverage is associated with reduced ED use, a lottery-based, controlled study

from Oregon found that newly enrolled beneficiaries actually increased their ED use, at least temporarily.<sup>1</sup> This finding is not surprising, since health insurance reduces financial barriers to being seen promptly, and the



#### Reasons for Visiting the Emergency Department.

Data are from the National Health Interview Survey 2011–2013. Respondents could select more than one answer. The sample is nonelderly adults (18 to 64 years of age) who have had an emergency department visit in the 12 months before they were interviewed. Persons who were known to have been uninsured in the previous 12 months are excluded from the Private and Medicaid categories.

newly enrolled Medicaid population has pent-up demand for care and a high burden of chronic disease. Although the contribution of ED use to cost growth is sometimes exaggerated, it remains a substantial source of health care costs, representing at least 5 to 6% of U.S. health expenditures.<sup>2</sup> Medicaid alone spends \$23 billion to \$47 billion annually on ED care,<sup>2</sup> and some of the sickest Medicaid enrollees are seen in the ED.

Broadly speaking, two approaches have been proposed for reducing use of the ED in this population. One focuses on making the ED more costly for patients to use; the other, on creating more robust alternatives to the ED. Although not incompatible, these approaches reflect different beliefs about why Medicaid beneficiaries use the ED for medical issues that could potentially be addressed elsewhere.

By imposing steep copayments for certain ED visits, the first approach aims to place responsibility on beneficiaries to make vigilant choices about when medical issues require emergency attention (see graph for reasons patients visit the ED). For instance, as part of its ACA Medicaid expansion, Indiana was granted permission by the Centers for Medicare and Medicaid Services (CMS) to undertake a demonstration project involving charging Medicaid recipients — many of whom have family incomes below the federal poverty level — \$8 for their first visit to the ED and \$25 for subsequent visits during the same year. The copayment applies when the visit is determined to be for “non-emergency” care, the patient did not receive prior authorization from his or her managed-care organization, or the emergency provider informed the patient that

the problem could be managed in another setting.

The logic behind increasing cost sharing for “non-emergency” ED visits is that it will motivate patients to use lower-cost care sites for most conditions, reserving the ED for times when they truly need immediate attention. This simple narrative, however, is challenged by research. States have had the option since 2005 of imposing copayments for Medicaid beneficiaries of up to \$15 for non-emergency ED use, yet the eight states that implemented these programs saw no reduction in ED visits by Medicaid recipients relative to other states.<sup>3</sup> Case studies of Medicaid cost sharing in other contexts similarly found that copayments alone do not reduce ED visits for diseases that can safely be treated in primary care settings. Analyses that have shown associations between copayments and reductions in “unnecessary” ED use are limited by their use of diagnosis or triage codes to determine retrospectively whether a visit qualifies as “nonurgent.”

One explanation for these findings is that even informed patients cannot necessarily translate their symptoms and history into a diagnosis, much less a prognosis. Patients present to the ED with symptoms that may signal an emergency, such as chest pain, and clinicians are able to rule out an emergency only after performing an evaluation and diagnostic tests. Indeed, 88% of all visits that are retrospectively determined to be for “non-emergency” (primary care treatable) diagnoses cannot be distinguished from true emergencies at the time of admission on the basis of the patient’s chief complaint.<sup>4</sup> It

is neither ethical nor prudent for clinicians to withhold care until they can determine whether a case is an emergency — and at that point opportunities for cost savings through diversion from the ED would probably be minimal.

Instead of requiring Medicaid patients to pay for a portion of their ED care, some states are trying to provide them with better alternatives to the ED. This strategy requires that beneficiaries have access to a primary care provider who can help prevent exacerbations of chronic illnesses such as asthma that might otherwise lead to acute crises. Well-managed systems can also provide prompt appointments to patients with time-sensitive health concerns that are not necessarily emergencies — such as a persistent, moderate headache that does not get better with over-the-counter medications.

At the core of this alternative approach to reducing ED visits are key components of the patient-centered medical home model, including care coordination, case management, extended hours, and walk-in visits. Medical-home initiatives emphasize prevention and post-acute care, and preliminary studies have shown these models to be effective in reducing ED use among Medicaid beneficiaries.<sup>5</sup> The ACA includes an optional program that gives states additional funding to support providers that develop “health homes” for Medicaid beneficiaries with multiple chronic physical conditions or severe mental illness. The program has been adopted by 16 states to date. Successful utilization of medical-home initiatives to reduce ED visits will depend on access to

providers who are willing to take Medicaid patients. Among other things, this approach will require the establishment of new access points for Medicaid beneficiaries through the growth of community health centers; policies that increase physician participation in Medicaid, such as reimbursement at parity with Medicare rates; and better support for participating practices, ranging from financial incentives for providing after-hours coverage, to shared electronic health records, to integrated behavioral health services.

Medical homes can be augmented with other resources to improve ease of use. For example, transportation is a common barrier to receiving timely primary care for low-income patients, yet ironically states such as Indiana that are seeking to penalize patients for ED use have used the same waiver process to curtail nonemergency transportation. Facilitating access to non-emergency transportation — for instance, by providing patients with taxi vouchers, subway tokens, or paratransit access — is critical, given that many Medicaid beneficiaries live in communities that lack such accessible options as retail or urgent care clinics.

Additional resources are also needed for triaging patients' health concerns and providing care in alternative settings. Policymakers may look beyond the United States for promising models. France, for instance, triages callers to its “15” line (the medical portion of its 911-equivalent) to a lay dispatcher or an on-call physician who can provide medical advice over the phone. If medical advice is insufficient, the dispatcher can advise the pa-

tient to see his or her primary care physician or can dispatch a physician to deliver care in the patient's home or send an ambulance. Differences in health system financing between the two countries would make it difficult to adopt this triage system wholesale in the United States. But state Medicaid programs could create financial incentives for Medicaid managed-care organizations to provide a help line to assist patients in choosing appropriate treatments and venues.

ED waiting rooms impose a substantial time cost on people seeking care, yet more patients visit the ED every year. Burdening patients with a bill if the cause of their visit is retroactively deemed not to have been an emergency will probably prove neither equitable nor effective in directing patients to alternative settings and could lead to unintended consequences if patients avoid care out of fear of economic hardship. Given these ramifications and the ineffectiveness of past attempts to impose costs on Medicaid patients seeking ED care, the Obama administration's decision to approve demonstration projects involving high cost sharing and loss of transportation coverage is troubling. Instead, CMS might encourage state initiatives to develop robust ED alternatives. Although this approach requires more substantial changes to the health care system, it may be one of the most meaningful and sustained ways to improve the care of all medically or financially vulnerable Americans, especially Medicaid beneficiaries.

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