

treatment of Alzheimer's disease. In its single phase 3 trial, the drug slightly reduced the rate of cognitive decline in patients with Alzheimer's disease, though it did not prevent it.⁵ That study also showed that patients homozygous for apolipoprotein E4 (ApoE4) were considerably more likely than noncarriers to have cerebral edema, hemorrhage, or both when given the drug, and they appeared not to benefit from it at all. Subsequent case reports have also described severe cerebral hemorrhages in patients taking lecanemab with anticoagulants or tissue plasminogen activator. Follow-up studies are expected to clarify these potentially important risks.

Official product labeling for all prescription drugs in the United States is manufacturer-drafted but must be FDA-approved. Lecanemab's manufacturer chose not to not list ApoE4 homozygosity or anticoagulant use as contraindications in its label (only allergy to the drug is listed); a separate section suggests that ApoE4 testing "should be performed prior to initiation of treatment" but does not state that patients homozygous for ApoE4 shouldn't take the drug. In fact, the label

even indicates that the drug can still be given if such genotyping is not performed. As for anticoagulants, the label says only that "caution should be exercised" concerning use of the drug in patients taking these medications. In the FDA's apparent eagerness to pave the way for wide use of the drug 2 years after its disastrous approval of aducanumab (Aduhelm), a previous monoclonal antibody for Alzheimer's disease that provided little evident clinical benefit, the agency did not require lecanemab's manufacturer to state these risks more strongly. But if the FDA were to insist on clearer warnings, or if emerging data prompts it to do so in the future, will the latest Supreme Court decision limiting compelled speech now hamper the agency's ability to require such statements, for fear of violating the manufacturer's First Amendment rights?

The implications of the 303 *Creative* decision for vulnerable groups thus extend far beyond same-sex couples seeking to commission a wedding website, or pregnant women anxious to learn about their options. When it comes to understanding the risks of the medications we use, all

prescribers and patients could now become vulnerable groups. It's not too early to wonder whether the power that Congress has vested in the FDA to ensure that drug makers accurately describe their products' side effects might before long also be limited by the courts as a form of prohibited "compelled speech."

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A Chance to Modernize Health Care behind Bars — Section 1115 Medicaid Inmate Exclusion Waivers

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In 2023, California and Washington became the first states to receive waivers from the Centers for Medicare and Medicaid Services (CMS) regarding the Medicaid Inmate Exclusion Policy, a federal provision that generally prohibits Medicaid from paying for health care for people who are incarcerated. Roughly 2 mil-

lion Americans were incarcerated on any given day in 2020 and 2021.¹ People who are incarcerated are disproportionately poor and members of marginalized racial or ethnic groups, and they have elevated rates of mental illness, substance use disorders, and other chronic diseases.¹ Engaging members of this population in

better-coordinated care as they leave jail or prison could improve postrelease use of preventive and chronic-disease care at safety-net clinics and support improved health outcomes.

Under Section 1115 of the Social Security Act, CMS can grant states flexibility in statutory provisions on a demonstration basis.

Section 1115 waivers of the Medicaid Inmate Exclusion Policy could demonstrate the viability of expanding Medicaid eligibility to people who are incarcerated and present an important opportunity to modernize carceral health care in the United States. The California waiver, for example, covers various reentry-related health services for an estimated 200,000 people per year during the 90 days before release from jail or prison.² At least 13 additional states are seeking Inmate Exclusion waivers.² Providing coverage in a new context is a complicated undertaking for states. To support applications for such waivers, CMS released guidance in April 2023 outlining broad programmatic goals, including increased continuity of coverage and services, improved care coordination, and reduced hospital use and mortality in the postrelease period. The guidance lays out three required benefits: comprehensive case management, prerelease provision of medication for substance use disorder (referred to by CMS as medication-assisted treatment [MAT]), and provision of a 30-day supply of all prescribed medications to people at the time of release (see table).¹ It also defines operational expectations related to data sharing, monitoring, and evaluation.

Beyond these required benefits, however, the CMS guidance isn't especially prescriptive. This lack of specificity may reflect the challenges associated with reforming carceral health care — which often operates with insufficient staffing, tight budgets, and a limited set of covered services — as well as the circumstances of incarceration. For example, length of confinement is often unpredictable, and states are working with CMS to define

when people are entering the period in which they would be eligible for Medicaid coverage before release. The guidance acknowledges that many facilities will require a phase-in period to adapt to standard billing and reimbursement procedures and the reality that medical staffing in jails and prisons often doesn't meet community standards. It provides considerable flexibility in required elements of the waivers, such as the requirement to provide medication for substance use disorder, urging programs “to use all available levers in their states to increase the availability of MAT as clinically appropriate” without mandating, for example, coverage of methadone and buprenorphine for all people who are incarcerated (as is required for Medicaid beneficiaries outside of carceral settings). These accommodations may be both necessary and beneficial in the short term, but it will be important for policymakers to recognize that federal funding provides critical leverage to improve the quality of carceral health care and to increase accountability among carceral agencies.

Ensuring that carceral health care is independently financed and operated would be one step toward modernizing care delivery. Health care contracts and budgets are generally overseen by security officials, many of whom have limited expertise in and experience with health care provision. Such officials often outsource care delivery to for-profit vendors that compete for contracts by underbidding their competitors and ultimately skimp on services. Medicaid funding has the potential to disrupt this model. As a condition of receiving funds, carceral agencies could be required to establish a finan-

cially independent oversight board or management group that administers the health services benefit and makes decisions about covered benefits and staffing. These requirements could be enforced by means of “conditions of participation” requirements that include governance standards similar to those applied to hospitals and other institutions that receive federal funding, which could help decouple the budgeting and operations of carceral health care from security operations.

In other high-income countries, carceral health care budgets are often administered by health agencies instead of corrections departments. For example, quality of care for people who were incarcerated improved when England shifted health care management from a prison authority to the National Health Service.³ Although it will always be necessary for carceral health care practitioners to collaborate with security staff, establishing operational independence could empower health care leaders to make coverage decisions without the need to accommodate or placate security officials and could support a clear division of responsibilities.

A second, related step would be to require ongoing, transparent health surveillance and quality-measurement programs as a condition of Medicaid funding. People who are incarcerated are currently excluded from all major national population-based health and health care surveys and statistics.⁴ States receiving Inmate Exclusion waivers will be required to compile data on Medicaid-funded services rendered under the waiver but aren't slated to engage in broader, systematic data collection. A bolder approach

Required Benefits for States Receiving Section 1115 Inmate Exclusion Waivers.	
Required Benefit	Example
Case management to assess and address physical, behavioral, and social health needs	A case manager determines that a person who is incarcerated has undiagnosed mental illness and is homeless. The case manager helps the person secure a spot in supportive housing and provides a referral to a mental health clinic.
Medication for substance use disorder	A person who is incarcerated in a county jail meets screening criteria for opioid use disorder. The jail offers the person a choice of medications, and the patient is ultimately started on buprenorphine at an appropriate dose.
30-Day supply of medications offered immediately on release	A person who is incarcerated has diabetes and asthma. On the day of release, prison health care staff hand the person 30-day supplies of each of the required medications.

would be to require states and localities to compile health care claims data sets that meet reporting standards used by CMS programs outside of carceral facilities. The creation of such data sets could permit the development of claims-based quality-of-care measures that are relevant to people who are incarcerated. Such measures could be similar to those focused on preventive care and management of chronic diseases that are already widely used in the Healthcare Effectiveness Data and Information Set. This information would provide greater clarity about the ongoing health needs of people who are incarcerated and permit the establishment of benchmarks for assessing quality-improvement efforts.

Finally, over the long term, clinicians working in jails and prisons could be included in value-based payment programs that are now widespread in Medicaid. In recent years, there has been a proliferation of new Medicaid initiatives that provide supplements or alternatives to traditional fee-for-service volume-driven payment models. For example, Medicaid programs have implemented value-based initiatives in which a percentage of the total payment directed to providers or managed

care organizations is conditioned on the attainment of particular quality metrics.⁵ Since incarceration often begins with a psychiatric or addiction-related crisis, value-based payments in jails and prisons could focus on crisis stabilization. Such efforts could reduce avoidable hospitalizations and improve continuity of medication use after release. Designing payment programs focused on improved postrelease outcomes is in keeping with the value proposition inherent in Inmate Exclusion waivers — that Medicaid can save some money during the reentry period by investing in better health care during incarceration. This goal may take time to realize, however, and up-front spending on better care-management systems in the shorter term may be required to increase the carceral system's readiness to move toward value-based payment.

The recent Inmate Exclusion waivers granted to California and Washington represent a meaningful step toward greater care integration for people who are incarcerated. Although the waivers cover only a limited prerelease period, they could be a stepping stone to the partial or complete repeal of the Medicaid Inmate Exclusion Policy — a proposal with bipartisan support that is

under serious consideration in Congress. The repeal of this policy would represent an unprecedented investment of federal funds in the health of people who are incarcerated. To ensure that investments made under future waivers or congressional action have the greatest possible effect, Medicaid officials could use the leverage associated with federal funding to improve the conditions under which health care is delivered in jails and prisons. Doing so could support the health of millions of Americans and the communities to which most of them will return.

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