NEW FEDERAL STANDARDS AIMED AT PREVENTING DISCRIMINATION IN ALL FEDERAL HEALTH PLANS AND PROGRAMS DISAPPOINTED PATIENT ADVOCACY GROUPS THAT HAD HOPED FOR REQUIREMENTS DictATING EXPANSIVE FORMULARIES. THEY WANTED THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) TO INSTRUCT MEDICARE, MEDICAID, MARKETPLACE AND COMMUNITY HEALTH PLANS, AND OTHERS RECEIVING FEDERAL FUNDS THAT CERTAIN FORMULARY RESTRICTIONS, SUCH AS PLACING EXPENSIVE DRUGS ON THE HIGHEST TIER, WERE DISCRIMINATORY. BUT THE HHS DECLINED TO ADOPT SUCH STANDARDS. THAT WAS A VICTORY FOR INSURANCE COMPANIES AND THEIR PHARMACY BENEFIT MANAGERS. BUT NEITHER DID THE HHS ESTABLISH A “SAFE HARBOR” WHERE DRUG BENEFIT ACCESS PRACTICES APPROVED BY P&T COMMITTEES WOULD BE DEEMED COMPLIANT WITH THE NEW ANTIDISCRIMINATION STANDARDS.

“We are disappointed that HHS did not do a better job at specifically defining discrimination in plan benefit design,” says Carl Schmid, Deputy Executive Director of the AIDS Institute and leader of the I Am Essential Coalition of nearly 200 patient advocacy groups. “Despite the many benefits of the ACA [Affordable Care Act] and its prohibition on denying coverage to beneficiaries with a pre-existing condition, some insurance plans are finding ways to discriminate against patients, particularly those with chronic and serious health conditions. Those practices should be defined and clearly prohibited. However, we are pleased that HHS reiterated they will review plans for discriminatory practices on a case-by-case basis through their enforcement activities, and identified a number of examples of possible discriminatory plan designs. We urge the administration to rigorously use their oversight and enforcement tools.”

The HHS Office for Civil Rights (OCR), which was tasked with writing the rule, acknowledged in the final version that it was under pressure to define discriminatory “benefit design.” But it said doing so would be “overly prescriptive.” Nor would it codify examples of discriminatory benefit designs because determining whether a particular design results in discrimination will be a fact-specific inquiry that OCR will conduct in enforcing Section 1557 of the Patient Protection and Affordable Care Act (PPACA).

This new rule will require hospitals, health plans, physician offices, pharmacies, state and local programs, and others to do things they don’t do under existing civil rights laws in terms of notification, training, and translation services for patients. The HHS estimates the industry-wide cost at $558 million over two years, with pharmacies spending about $10 million of that. The rule’s main impact may be extending civil rights coverage to transgender individuals.

Though the OCR declined to list discriminatory benefit designs, it said it has previously given examples when setting standards for particular federal health programs. For example, the final rule the Centers for Medicare and Medicaid Services (CMS) issued governing health benefits in 2016 for marketplace plans said it would be discriminatory to place most or all prescription medications that are used to treat a specific condition on the highest-cost formulary tiers. A separate notice issued in 2015 providing guidance to marketplace plans cited another example of discrimination: requiring prior authorization and/or step therapy for most or all medications in a drug class, such as anti-human immunodeficiency virus protease inhibitors, regardless of medical evidence.

While the OCR wasn’t sympathetic to patient advocacy groups’ requests to set more specific tiering and prior authorization restrictions, neither did it satisfy the insurance industry, which wanted the final rule to establish a “safe harbor” where formularies set up by P&T committees were deemed to be nondiscriminatory. Health insurance companies operating in the marketplace must already meet specific PPACA formulary and P&T committee requirements that will be upgraded in 2017 to require specific policies for P&T committee structure and operations, the formulary exceptions process, and the accessibility of formulary information. So some insurers argued that as long as they meet those PPACA standards in all their health plans—whether it is Medicare, Medicaid, marketplace, or any other federally funded program—they should not face enforcement action under the nondiscrimination rule.

The OCR replied that it sees the wisdom of “efficiencies inherent in harmonizing regulations” across federally funded health plans. But the final rule said it is inappropriate to define requirements under federal law based on what could be the varying, and potentially changing, requirements of different states’ approaches. States often have leeway to determine benefits in federal health programs. “As to other federal laws, OCR will give consideration to an entity’s compliance with the requirements of other federal laws where those requirements overlap with Section 1557,” the OCR said.

The new rule is the latest example of HHS hesitancy to wade further into the politically fraught area of drug access and formulary construction. Congress has ramped the department’s knuckles in the past for trying to change formulary structure, most notably when the CMS tried to drop antidepressants and immunosuppressants from the six drug classes for which Part D program formularies must provide “all or substantially all” the drugs. Congress slapped its hands then, and the specter of that happening again probably gave some HHS officials nightmares.

REFERENCE