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Medicare Rulemaking After Azar v. Allina Health Services
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Client Alert

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The Medicare Program, established in 1965, initially seemed simple: provide health care for senior citizens by paying hospitals and doctors directly for the care the seniors required. Initially, there were two parts to Medicare: Part A hospital/acute care payments and Part B physician and outpatient payments. A senior citizen who signed up for Medicare Part A and Part B could obtain medical care and assign the senior's right to Medicare payment to the provider of care, and this would relieve the senior from worries about paying for the care received.

But this simple program is now a major entitlement program, and as the costs of Medicare increased over the years, the Department of Health and Human Services (DHHS) sought various means to cut the Medicare cost curve and reduce the Medicare impact on federal spending. One new program to reduce costs was implemented through a new Medicare Part C adopted in 1997. Under Part C, DHHS contracts with private insurance companies to manage the Medicare benefit within a pre-paid monthly stipend for each of the insurers' Part C enrollees. The Part C program's benefits replaced the seniors' direct assignment of payments for services under Parts A and B.

Gradually, CMS realized that Medicare Part C had a specific consequence for another part of the Medicare program, the Medicare Disproportionate Share Hospital (DSH) payments. Hospitals that qualify for DSH payments are those that serve many of the poorest patients—those who are also receiving disability payments under the Social Security Program. Traditionally, a hospital would create a ratio of the care provided to these very poor patients as a percentage of its overall Medicare Part A services, and then Medicare would offer an additional DSH payment to those who disproportionately served this population to recognize the extra care and attention these patients require. But beginning in 2004, as the acute care services previously paid for only under Part A began to be diverted into the Part C programs, CMS wanted to recognize these Part C services in the hospitals' DSH ratio. The net effect of including Part C would be to reduce the proportion of total hospital Medicare services that would be attributable to DSH patients—arguably back to the original acute care/disabled population ratio, without regard to the Medicare payment program. The government estimated the savings from this change in the billions of dollars.

But not so fast, wrote Justice Gorsuch in *Azar v. Allina Health Services* (June 3, 2019): DHHS did not follow proper rulemaking procedures to change the DSH formula and to include Part C acute care reimbursements in the DHS ratio. For the Medicare program, Congress has imposed a Medicare-specific rulemaking statute that must be followed to facilitate notice and comments. This statute requires a 60-day notice and comment period for any "rule, requirement, or other statement of policy . . . that establishes or changes a *substantive legal standard* governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under [Medicare]." 42 U.S.C. §1395hh(a)(2) (*italics added*). The Administrative Procedures Act (APA) also uses the term "substantive legal standard," but there is no definition of the term in either the Medicare rulemaking statute or the APA. The government argued that the APA might allow a change to a "substantive legal standard" through interpretive guidance rather than through formal rulemaking, and that this process should be allowed for the Medicare rulemaking process also. Justice Gorsuch reviewed the differences between the APA and the Medicare rulemaking statute and concluded that Congress did not intend for the term "substantive legal standard" to be interpreted identically in the two systems. Therefore, the justice reasoned, the 2014 CMS interpretative Statement of Policy that proposed to change the "substantive legal standard" to calculate the required "payment for services" in the DSH program

required adherence to the specific and more cumbersome notice and comment requirements of the Medicare rulemaking statute. CMS had not followed these requirements, and therefore it will not be allowed to utilize the change in the DSH ratio calculation.

This case demonstrates the current court's jurisprudential style of strict statutory construction. Justice Gorsuch adhered closely to and compared the language of the Administrative Procedures Act and the Medicare rulemaking statute to reach and explain the court's conclusion. He had little use for arguments based upon the legislative history of the Medicare rulemaking statute, which he called ambiguous. Quoting *Milner v. Department of Navy* (2011), the justice explained that "even those of us who believe that clear legislative history can 'illuminate ambiguous text' won't allow 'ambiguous legislative history to muddy clear statutory language.'" Despite any fundamental distrust that CMS or others may have that rulemaking can be effective or that Congress can be trusted to legislate and resolve issues that will arise as the Medicare program, Justice Gorsuch wrote, "[i]f the government doesn't like Congress's notice-and-comment policy choices, it must take its complaints [to Congress]."

The Allina Health decision recognizes that "[n]otice and comment gives affected parties fair warning of potential changes in the law and an opportunity to be heard on those changes—and it affords the agency a chance to avoid errors and make a more informed decision . . . when it comes to a program where even minor changes to the agency's approach can impact millions of people and billions of dollars in ways that are not always easy for regulators to anticipate." The case thus tempers the speed at which DHHS' agencies may change the regulatory framework for administration of the Medicare program, and increases the stability of these programs as public opinion changes or solidifies. In an era in which some lament the slow pace of change, and others worry that change is moving too quickly, the court's reassertion of the give and take of legislative and agency actions to administer major programs is a reminder of the fundamentally deliberative pace that is determined by the balance of powers under our Constitution.

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