



Health Care Litigation ADVISORY ■

JANUARY 14, 2021

HHS Places Additional Limits on the Use of Guidance Documents

by [Matt Dowell](#), [Bill Jordan](#), and [Jason Popp](#)

Over the years, it has been incredibly frustrating for health care companies to face punitive False Claims Act (FCA) liability or administrative enforcement for an alleged violation of something in a “guidance document” or manual that has never been subjected to notice-and-comment rulemaking. Even the Department of Health and Human Services (HHS) now recognizes the inherent unfairness and arbitrariness that can result from using these informal policies and documents along with the hammer of government enforcement.

On Tuesday, January 12, HHS announced a [new rule](#) that restricts the agency from pursuing enforcement actions that are based on alleged violations of the agency’s sub-regulatory guidance materials. The new rule [mirrors](#) recent Department of Justice (DOJ) policy limiting the use of guidance documents in enforcement actions and a Supreme Court decision restricting HHS’s ability to sidestep formal rulemaking.

The new rule has three important components. First, it prohibits HHS from using “guidance documents to impose binding requirements ... except as expressly authorized by law or as expressly incorporated into a contract.” Second, the rule prevents HHS from applying standards or requirements unless they have been publicly announced. Third, the rule requires HHS in most instances to notify regulated entities—and give them an opportunity to respond in writing—before instituting an enforcement action.

The new rule is “one component of the Department’s broader regulatory reform initiative,” and it follows [a rule issued in December 2020](#) that requires HHS to post guidance documents on an [online repository](#) and formalizes the process by which the agency promulgates new guidance materials. The December 2020 rule further prohibits HHS from deviating from explicit statutory or regulatory requirements by: (1) establishing new legal obligations in a guidance document; and (2) using guidance documents to require a regulated entity to take action (or refrain from taking action). The earlier rule also explains how HHS must issue new guidance documents, requires HHS to publish guidance documents on an online portal, and allows any interested parties to petition the agency to withdraw or modify any guidance document.

These rules follow policy announcements from the DOJ, which [recently changed its policy](#) to similarly prohibit bringing civil or criminal enforcement actions based on “mere noncompliance with guidance documents.” The Supreme Court in *Azar v. Allina Health Services* likewise concluded that HHS had to follow the rulemaking process when issuing new substantive legal standards.

This advisory is published by Alston & Bird LLP to provide a summary of significant developments to our clients and friends. It is intended to be informational and does not constitute legal advice regarding any specific situation. This material may also be considered attorney advertising under court rules of certain jurisdictions.

The new rule provides important protections to providers and health care entities. But the rule is not a panacea. HHS can blunt the rule's impact by expressly incorporating more guidance documents (like Medicare manuals) in its contracts. Moreover, "guidance documents" do not include instructions or requirements imposed by Medicare administrative contractors. It is also uncertain how courts will apply the rule in cases brought by FCA relators. Prior attempts to use similar DOJ guidance and the Supreme Court's *Azar* decision in FCA litigation have had mixed results. In addition, it remains to be seen how the new rule and its December 2020 counterpart may fare in the incoming Biden Administration or the new Congress. Regardless, this is a positive step in the right direction for providing more certainty around enforcement decisions.

You can subscribe to future *Health Care Litigation* advisories and other Alston & Bird publications by completing our [publications subscription form](#).

Alston & Bird has launched the [Digital Transformation of Health Care](#), a new initiative that advances our commitment to an industry approach to providing legal services in the health care space. Our health care and technology teams can assist with establishing or significantly growing telehealth capabilities and navigating the regulatory landscape.

If you have any questions, or would like additional information, please contact any of the following:

Health Care Litigation Team

Brian D. Boone
704.444.1106
202.239.3206
brian.boone@alston.com

R. Joseph Burby IV
404.881.7670
joey.burby@alston.com

Mark T. Calloway
704.444.1089
mark.calloway@alston.com

Kimberly K. Chemerinsky
213.576.1079
kim.chemerinsky@alston.com

Daniel G. Jarcho
202.239.3254
daniel.jarcho@alston.com

William H. Jordan
404.881.7850
202.756.3494
bill.jordan@alston.com

Edward T. Kang
202.239.3728
edward.kang@alston.com

Meredith Jones Kingsley
404.881.4793
meredith.kingsley@alston.com

Andrew J. Liebler
404.881.4712
andrew.liebler@alston.com

Wade Pearson Miller
404.881.4971
wade.miller@alston.com

Paul N. Monnin
404.881.7394
paul.monnin@alston.com

Jason D. Popp
404.881.4753
jason.popp@alston.com

T.C. Spencer Pryor
404.881.7978
spence.pryor@alston.com

Samuel R. Rutherford
404.881.4454
sam.rutherford@alston.com

Frank E. Sheeder
214.922.3420
frank.sheeder@alston.com

ALSTON & BIRD

WWW.ALSTON.COM

© ALSTON & BIRD LLP 2021

ATLANTA: One Atlantic Center ■ 1201 West Peachtree Street ■ Atlanta, Georgia, USA, 30309-3424 ■ 404.881.7000 ■ Fax: 404.881.7777
BEIJING: Hanwei Plaza West Wing ■ Suite 21B2 ■ No. 7 Guanghua Road ■ Chaoyang District ■ Beijing, 100004 CN ■ +86.10.85927500
BRUSSELS: Level 20 Bastion Tower ■ Place du Champ de Mars ■ B-1050 Brussels, BE ■ +32 2 550 3700 ■ Fax: +32 2 550 3719
CHARLOTTE: One South at The Plaza ■ 101 South Tryon Street ■ Suite 4000 ■ Charlotte, North Carolina, USA, 28280-4000 ■ 704.444.1000 ■ Fax: 704.444.1111
DALLAS: Chase Tower ■ 2200 Ross Avenue ■ Suite 2300 ■ Dallas, Texas, USA, 75201 ■ 214.922.3400 ■ Fax: 214.922.3899
FORT WORTH: 3700 Hulen Street ■ Building 3 ■ Suite 150 ■ Fort Worth, Texas, USA, 76107 ■ 214.922.3400 ■ Fax: 214.922.3899
LONDON: 5th Floor ■ Octagon Point, St. Paul's ■ 5 Cheapside ■ London, EC2V 6AA, UK ■ +44.0.20.3823.2225
LOS ANGELES: 333 South Hope Street ■ 16th Floor ■ Los Angeles, California, USA, 90071-3004 ■ 213.576.1000 ■ Fax: 213.576.1100
NEW YORK: 90 Park Avenue ■ 15th Floor ■ New York, New York, USA, 10016-1387 ■ 212.210.9400 ■ Fax: 212.210.9444
RALEIGH: 555 Fayetteville Street ■ Suite 600 ■ Raleigh, North Carolina, USA, 27601-3034 ■ 919.862.2200 ■ Fax: 919.862.2260
SAN FRANCISCO: 560 Mission Street ■ Suite 2100 ■ San Francisco, California, USA, 94105-0912 ■ 415.243.1000 ■ Fax: 415.243.1001
SILICON VALLEY: 1950 University Avenue ■ Suite 430 ■ East Palo Alto, California, USA 94303 ■ 650.838.2000 ■ Fax: 650.838.2001
WASHINGTON, DC: The Atlantic Building ■ 950 F Street, NW ■ Washington, DC, USA, 20004-1404 ■ 202.239.3300 ■ Fax: 202.239.3333