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New Developments Further Limit Use of Agency Guidance in Medicare Enforcement Actions

***By* Brad Smyer *and* Matthew Dowell**

A new internal memorandum from the U.S. Department of Health and Human Services (HHS) discourages the agency from basing enforcement actions on guidance documents that are "not closely tied to statutory or regulatory standards." This directive has potentially far-reaching effects for health care providers and suppliers because of the prevalence of Medicare local coverage determinations (LCDs) and other "sub-regulatory" government guidance documents and manuals that establish health care reimbursement rules.

The new HHS memo builds on two years of efforts by the U.S. Department of Justice (DOJ) to limit the reach of sub-regulatory agency guidance. In 2017, former U.S. Attorney General Jeff Sessions issued a memorandum preventing the DOJ from issuing "guidance documents that purport to create rights or obligations binding on persons outside the Executive Branch." In 2018, the Brand Memorandum expanded on this theme and prohibited civil enforcement actions based on "noncompliance with guidance documents." The Brand Memorandum has been incorporated into the Justice Manual, the guidebook for DOJ attorneys.

The HHS memo comes in response to the U.S. Supreme Court's recent disapproval of HHS's attempt to change Medicare reimbursement by posting revisions online. (See *Azar v. Allina Health Servs.*, ___U.S.___ (2019), 139 S. Ct. 1804, 1808, 204 L. Ed. 2d 139, 144.) The Court based its decision on the Medicare Act's requirement that a "substantive legal standard" be promulgated through formal rulemaking. The Court did not define "substantive legal standard," but affirmed a lower court ruling that held that the term "at a minimum includes a standard that creates, defines, and regulates the rights, duties, and powers of parties."

Earlier this month, a federal court in Pennsylvania relied on the Court's reasoning in *Allina* to dismiss a whistleblower's claims under the False Claims Act. (See *Polansky v. Exec. Health Res., Inc.* No. 12-CV-4239, 2019 U.S. Dist. LEXIS 192332, at *4 (E.D. Pa. Nov. 5, 2019).) The whistleblower alleged that the defendant did not follow Medicare criteria when admitting inpatients. The Pennsylvania court granted summary judgment on the claims because the relevant inpatient standards were "contained in agency manuals that had not been promulgated pursuant to notice and comment, as required by the Medicare Act." The court reasoned that the inpatient criteria was a "substantive legal standard" because it "creates, defines, and regulates the rights, duties, and powers of parties."

In the aftermath of *Allina*, the new HHS memo recognizes that *Allina* forecloses enforcement actions based solely on guidance documents that create or alter "substantive legal standards." The agency distinguishes between guidance documents that "are not closely tied to statutory or regulatory standards"—which cannot form the basis of an enforcement action—and those that merely "provide additional clarity without creating a new non-statutory or non-regulatory norm." The memo leaves open the question of what it means to be "closely tied." A likely interpretation is that the guidance cannot add new substantive requirements. Even then, HHS recognizes that "a guidance document issued consistent with *Allina* may not be used as the sole basis for an enforcement action, although it may be relevant for other purposes, such as scienter or materiality." Importantly, the HHS memo specifically states that "government enforcement actions based solely on LCDs are generally unsupportable."

Going forward, providers and suppliers should consider how best to use *Allina*, the new HHS memo, and related DOJ policy to limit enforcement actions based on requirements found only in LCDs, reimbursement manuals from the Centers for Medicare & Medicaid Services, or other sub-regulatory guidance. Providers and suppliers should also consider whether they agreed by contract to comply with these sub-regulatory requirements.

This new guidance impacts not only enforcement by putative whistleblowers and the DOJ, but also administrative actions by HHS and its components like the Office of Inspector General and the Office of Civil Rights. It could also lead to a significant increase in rulemaking activity by the agency.

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If you have any questions or would like additional information please contact your Alston & Bird attorney or any of the following:

Adam Biegel
202.239.3692
adam.biegel@alston.com

Matthew L.J.D. Dowell
404.881.7434
matt.dowell@alston.com

Cathy Burgess
202.239.3648
cathy.burgess@alston.com

Angie Burnette
404.881.7665
angie.burnette@alston.com

Mark Calloway
704.444.1089
mark.calloway@alston.com

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

Sarah Ernst
404.881.4940
sarah.ernst@alston.com

Brian Frey
202.239.3067
brian.frey@alston.com

Larry Gage
202.239.3614
larry.gage@alston.com

Joyce Gresko
202.239.3628
joyce.gresko@alston.com

Elinor Hiller
202.239.3766
elinor.hiller@alston.com

Russ Hilton
404.881.7866
russell.hilton@alston.com

Michael Hoernlein
704.444.1041
michael.hoernlein@alston.com

Brett Jaffe
212.210.9547
brett.jaffe@alston.com

Dan Jarcho
202.239.3254
daniel.jarcho@alston.com

William Jordan
404.881.7850
202.756.3494
bill.jordan@alston.com

Edward Kang
202.239.3728
edward.kang@alston.com

Meredith Jones Kingsley
404.881.4793
meredith.kingsley@alston.com

Jenny Kramer
212.210.9420
jenny.kramer@alston.com

Jane Lucas
202.239.3229
jane.lucas@alston.com

Dawnmarie Matlock
404.881.4253
dawnmarie.matlock@alston.com

Emily McGowan
704.444.1027
emily.mcgowan@alston.com

Wade Pearson Miller
404.881.4971
wade.miller@alston.com

Paul Monnin
404.881.7394
paul.monnin@alston.com

Michael Park
202.239.3630
michael.park@alston.com

Kimberly Peretti
202.239.3720
kimberly.peretti@alston.com

Jason Popp
404.881.4753
jason.popp@alston.com

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

J. Mark Ray
404.881.7739
mark.ray@alston.com

Mark Rayder
202.239.3562
mark.rayder@alston.com

Samuel Rutherford
404.881.4454
sam.rutherford@alston.com

Marc Scheineson
202.239.3465
marc.scheineson@alston.com

Frank Sheeder
214.922.3420
frank.sheeder@alston.com

Bob Siggins
202.239.3836
bob.siggins@alston.com

Bradley M. Smyer
214.922.3459
brad.smyer@alston.com

John Snyder
202.239.3960
john.snyder@alston.com

Rob Stone
404.881.7270
rob.stone@alston.com

Tim Trysla
202.239.3420
tim.trysla@alston.com

Thomas Walker
704.444.1248
919.862.2212
thomas.walker@alston.com

Esther Yu
404.881.4401
esther.yu@alston.com

ALSTON & BIRD

WWW.ALSTON.COM

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 8592 7500
BRUSSELS: Level 20 Bastion Tower ■ Place du Champ de Mars ■ B-1050 Brussels, BE ■ +32 2 550 3700 ■ Fax: +32 2 550 3719
CHARLOTTE: Bank of America 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
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: 950 Page Mill Road ■ Palo Alto, California, USA 94304-1012 ■ 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