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The Burden of a Good Idea: Examining the Impact of Unfunded Federal Regulatory Mandates on Medicare Participating Hospitals

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I. Introduction

Health care costs are on the rise.[1] In 1960, the United States spent $9 billion on hospital care.[2] Since then, hospital related spending has grown exponentially.[3] In 2015, the United States spent over $1 trillion on hospital care,[4] with $359.9 billion of those payments coming from the federal Medicare program for the aged and disabled.[5] Researchers have long tried to understand the exact causes of rising health care costs. While many have closely examined the costs associated with population demographics, medical innovation, prescription drug costs, overutilization of

1. *See Health Spending Explorer*, PETERSON-KAISER HEALTH SYS. TRACKER, https://www.healthsystemtracker.org/interactive/?display=U.S.%2520%2524%2520Billions&service=Hospitals%252CPhysicians%2520%2526%2520Clinics%252CPrescription%2520Drug&source=Total%2520National%2520Health%2520Expenditures&tab=0 (last visited Apr. 16, 2018) (showing a rise in U.S. health expenditures in hospitals, physicians offices, and clinics, and on prescription drugs from 1960 to 2016) (on file with the Washington & Lee Journal of Civil Rights & Social Justice).

2. *Id.*

3. *See id.* (referring to an increase in U.S. hospital expenditures of more than 1,200%).

4. *Id.*

5. CTRS. FOR MEDICARE & MEDICAID SERVS., CMS FAST FACTS 3 (Jan. 2018).

services, and fraud or abuse,[6] there is one driving force that does not receive sufficient attention—federal regulatory burden.[7]

Hospitals and other health care providers that participate in the Medicare program are heavily regulated by over thirty different federal agencies.[8] While the primary goal of these regulatory efforts is to protect patient safety and promote access to quality health care services, the burden imposed by these regulatory efforts is both "substantial and unsustainable."[9] One recent report estimated administrative costs, including the costs of

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6. *See, e.g.*, Peter Olson & Louise Sheiner, *The Hutchins Center Explains: Prescription Drug Spending*, BROOKINGS INST. (April 26, 2017), https://www.brookings.edu/blog/up-front/2017/04/26/the-hutchins-center-explains-prescription-drug-spending/ (describing "recent trends in drug spending, what's driving them, and what role the government policy plays") (on file with the Washington & Lee Journal of Civil Rights & Social Justice); *see also* TRICIA NEUMAN ET AL., THE RISING COST OF LIVING LONGER: ANALYSIS OF MEDICARE SPENDING BY AGE FOR BENEFICIARIES IN TRADITIONAL MEDICARE 1 (Jan. 2015), http://files.kff.org/attachment/report-the-rising-cost-of-living-longer-analysis-of-medicare-spending-by-age-for-beneficiaries-in-traditional-medicare (observing Medicare spending data available for beneficiaries) (on file with the Washington & Lee Journal of Civil Rights & Social Justice); *see also* BIPARTISAN POL'Y CTR., WHAT IS DRIVING U.S. HEALTH CARE SPENDING? AMERICA'S UNSUSTAINABLE HEALTH CARE COST GROWTH 6–7 (Sept. 2012), https://bipartisanpolicy.org/wp-content/uploads/sites/default/files/BPC%20Health%20Care%20Cost%20Drivers%20Brief%20Sept%202012.pdf (identifying "health care cost drivers" that are responsible for high health care costs) (on file with the Washington & Lee Journal of Civil Rights & Social Justice).

7. *See* AMERICAN HOSP. ASS'N, REGULATORY OVERLOAD: ASSESSING THE REGULATORY BURDEN ON HEALTH SYSTEMS, HOSPITALS AND POST-ACUTE CARE PROVIDERS 7 (Oct. 2017) [hereinafter AHA REGULATORY OVERLOAD REP.], https://www.aha.org/system/files/2018-02/regulatory-overload-report.pdf ("Every day, health systems, hospitals, and post-acute care (PAC) providers confront the daunting task of complying with a mountain of federal regulations.") (on file with the Washington & Lee Journal of Civil Rights & Social Justice).

8. *See id.* at 9 (presenting a diagram depicting the relationships between "federal agencies with regulatory authority impacting health systems, hospitals, and PAC providers").

9. *See id.* at 2–3, 7 (explaining the purpose of federal regulation with which health systems, hospitals, and post-acute care providers must comply); *see also* Letter from Thomas P. Nickels, Executive Vice President, American Hospital Association, to the Hon. Pat Tiberi, Charmain, Subcommittee on Health, H.R. 1 (Aug. 25, 2017) [hereinafter AHA Letter to Tiberi], https://www.aha.org/system/files/advocacy-issues/letter/2017/170825-let-nickels-tiberi-regulatory-relief.pdf [hereinafter AHA Letter to Tiberi] ("[T]he scope of changes required by the new regulations is beginning to outstrip the field's ability to absorb them.") (on file with Washington & Lee Journal of Civil Rights & Social Justice).

adopting and complying with health care regulations, now account for over twenty-five percent of annual hospital spending in the United States, or more than $215 billion a year.[10] Further, a recent study by the American Hospital Association (AHA) noted that "[a]n average sized community hospital now spends nearly over $7.6 million annually to support compliance with . . . federal regulations."[11]

Hospital participation in the Medicare program is voluntary.[12] Yet very few hospitals are able to opt out of the Medicare program as a means of containing regulatory compliance costs. The vast majority of hospitals are heavily dependent on Medicare reimbursement to meet operational expenses.[13] Further, a substantial portion of the hospital patient census is the Medicare-insured elderly.[14] Hospitals are thus beholden to the Medicare program despite the associated federal regulatory burden.[15]

Many federal regulations are implemented without any agency-allocated funding to offset compliance costs.[16] Further, Medicare payment rates for hospital services are set prospectively and do not change in response to the hospital's actual cost, meaning Medicare itself also does not compensate hospitals for compliance associated costs.[17] Hospitals that participate in Medicare are thus regularly required to absorb the costs of novel federal regulations, or to pass those costs along to non-Medicare health care consumers.

This Article seeks to draw attention to the role that federal regulation plays in rising health care costs by providing two

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10. David U. Himmelstein et al., *A Comparison of Hospital Administrative Costs in Eight Nations: U.S. Costs Exceed All Others by Far*, 33 HEALTH AFF. 1586, 1591 (2014).

11. AHA REGULATORY OVERLOAD REP., *supra* note 7, at 4 (adding that hospitals likely spend well in excess of $7.6 million as this figure only reflects the subset of regulations examined in the study).

12. *See generally infra* Part II(0).

13. *See infra* Part II(0).

14. *See infra* Part II(0).

15. *See infra* Part II(0).

16. *See infra* Part III(0).

17. *See infra* Part III(0).

examples of recent regulations that imposed significant burdens on hospital providers participating in the Medicare program. In both examples, the regulations imposed substantial new requirements, yet the issuing agencies failed to assess the scope of the burden imposed as part of the rulemaking process. Further, those agencies did not allocate any funds to pay for compliance costs, nor did the Medicare program change its reimbursement to cover implementation costs associated with services for Medicare beneficiaries.

In the first example, this Article addresses novel regulations regarding translation and interpretation services for Limited English Proficiency (LEP) individuals.[18] These regulations were issued by Department of Health and Human Services (HHS) Office of Civil Rights (OCR) in 2016 to implement Section 1557 of the Patient Protection and Affordable Care Act (ACA).[19] As detailed below, these regulations place substantial new burdens on hospitals, yet the HHS OCR did not assess the compliance costs in the final rule issuing the regulations.[20] The HHS OCR also did not did not allocate any funding to pay for the regulatory requirements and hospitals were not compensated for compliance costs through Medicare payments for hospital services provided to the LEP individuals.[21]

In the second, this Article examines the Department of Justice's (DOJ) 2010 regulations regarding the provision of interpretation services and other auxiliary aids to deaf and hard of hearing hospital patients.[22] While hospitals have been required to provide interpretation and other auxiliary aids to patients since

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18. *See infra* Part 0. "Limited English proficiency" refers to "an individual whose primary language for communication is not English and who has a limited ability to read, write, speak, or understand English." 45 C.F.R. § 92.4 (2018).

19. *See* 45 C.F.R. § 92.1 (2016) ("Section 1557 . . . prohibits discrimination on the basis of race, color, national origin, sex, age or disability in certain health programs and activities.").

20. *See generally* Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31375 (proposed May 18, 2016) (codified at 45 C.F.R. § 92).

21. *Id.*

22. *See* Nondiscrimination on the Basis of Disability by Public Accommodations and in Commercial Facilities, 75 Fed. Reg. 56236, 56253–54 (proposed Sept. 15, 2010) (codified at 28 C.F.R. § 36) [hereinafter 2010 DOJ Fed. Reg. Notice] (detailing amendments to 28 § 36.303 Auxiliary aids and services).

the Americans with Disabilities Act (ADA) was passed in 1990 and the associated implementing regulations were issued in 1991, the 2010 regulations imposed time-consuming and costly new requirements.[23] Again, the federal government did not assess the compliance costs or allocate any funding to pay for the increased regulatory burden.[24] Hospitals again were not compensated for compliance under the Medicare payments for hospital services provided to deaf and hard of hearing beneficiaries.[25]

Part II of this Article will explore the scope of federal regulation of healthcare providers, and the burden these regulations place on hospital providers. Part II will also examine Medicare payment methodologies for general acute care hospitals and show that Medicare payments do not compensate hospitals for the costs associated with implementing new unfunded regulatory requirements related to care for Medicare patients. Part III of this Article will provide an in-depth overview the 2016 regulations related to the provision of translation and interpretation services to LEP individuals under Section 1557 of the ACA. Part IV will provide an in-depth overview of the DOJ's 2010 regulations related to the provision of interpretation services and other auxiliary aids to the deaf and hard of hearing under the ADA. Finally, Part V concludes that unfunded regulatory mandates are an important driver of costs in the health care system that warrant further study and continued scrutiny.

II. Background

The Centers for Medicare and Medicaid Services (CMS) is the single largest payer for health care in the United States.[26] CMS

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23. *See generally id.*

24. *Id.*

25. *Id.*

26. *See* CTRS. FOR MEDICARE & MEDICAID SERVS., CMS ROADMAPS FOR THE TRADITIONAL FEE-FOR-SERVICE PROGRAM: OVERVIEW 1 (Jan. 2016), https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/RoadmapOverview_OEA_1-16.pdf (explaining that CMS administers Medicare, Medicaid, and the State Children's Health Insurance Program (SCHIP), which provide health care benefits to nearly ninety million Americans) (on file with the Washington & Lee Journal of Civil Rights &

has estimated that in coverage year 2017 approximately fifty-eight million elderly and disabled individuals will obtain health insurance coverage through the traditional Medicare Program Part A and/or Part B programs.[27] In 2015, the most recent data available, nearly 7.7 million Medicare Part A beneficiaries obtained inpatient hospital care under Part A.[28] Further, 25.3 million Medicare Part B beneficiaries obtained outpatient hospital care under Part B.[29]

Hospitals that provide care to Medicare beneficiaries must comply with federal statutory and regulatory requirements as a condition of participation in the Medicare program.[30] Federal regulations are "largely intended to ensure that health care patients receive safe, high-quality care."[31] However, hospitals have long asserted that the number and nature of regulatory requirements are "substantial and unsustainable."[32]

Every year, hospitals are subjected to additional federal regulatory requirements. For example, in 2016 alone, CMS released "[forty-nine] rules pertaining to hospitals and health systems, comprising almost 24,000 pages of text."[33] These numbers do not include the additional guidance documents issued by the agency to help implement new administrative policies.[34] Further,

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Social Justice).

27. *See* CMS FAST FACTS, *supra* note 5, at 1 ("Part A (hospital insurance) covers most medically necessary hospital, skilled nursing facility, home health, and hospice care."); *see also What Does Medicare Cover (Parts A, B, C, and D)?*, MEDICARE INTERACTIVE, https://www.medicareinteractive.org/get-answers/introduction-to-medicare/explaining-medicare/what-does-medicare-cover-parts-a-b-c-and-d (last visited Apr. 16, 2018) ("Part B (medical insurance) covers most medically necessary doctors' services, preventative care, durable medical equipment, hospital outpatient services, laboratory tests, x-rays, mental health care, and some health and ambulance services.") (on file with the Washington & Lee Journal of Civil Rights & Social Justice).

28. CMS FAST FACTS, *supra* note 5, at 3.

29. *Id.*

30. *See* 42 C.F.R. § 482.11(a) (2018) ("The hospital must be in compliance with applicable Federal laws related to the health and safety of patients.").

31. AHA REGULATORY OVERLOAD REP., *supra* note 7, at 3.

32. AHA Letter to Tiberi, *supra* note 9, at 1.

33. *Id.*

34. *See id.* (referring to "sub-regulatory guidance (FAQs, blogs, etc.) to implement new administrative policies").

while CMS is one of the primary regulatory agencies for hospitals and health care providers, other federal agencies have also added substantially to regulatory burden in recent years.[35] The AHA has identified over thirty federal agencies with regulatory or oversight authority impacting hospitals.[36]

While regulatory burden is ever-increasing, hospitals often do not receive additional pay to offset implementation costs.[37] These unfunded regulatory mandates place a strain on hospital operations. Studies have shown that Medicare chronically underpays some hospitals for the costs of providing services to Medicare beneficiaries.[38] As unfunded regulatory burden increases, hospitals are further underpaid by CMS for the provision of Medicare services. Hospitals must look to other sources of revenue to offset these costs, resulting in rising health care costs for all patients.[39] Thus, regulatory burden is an important driver of increasing health care costs across the health care delivery system.

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35. *See* AHA REGULATORY OVERLOAD REP., *supra* note 7, at 7 (listing a sample variety of federal agencies that also issue federal health care regulations).

36. *See id.* at 9 (depicting the numerous "federal agencies with regulatory authority impacting health systems, hospitals, and PAC providers").

37. *See infra* Part III(C. Medicare *Payment for Hospital Services is Not Responsive to Novel Regulatory Burden*

38. *See* AMERICAN HOSP. ASS'N, UNDERPAYMENT BY MEDICARE AND MEDICAID FACT SHEET 2 (Dec. 2017) [hereinafter AHA UNDERPAYMENT FACT SHEET], https://www.aha.org/system/files/2018-01/medicaremedicaidunderpmt%202017.pdf ("In the aggregate, both Medicare and Medicaid payments fell below costs in 2016 . . . .") (on file with the Washington & Lee Journal of Civil Rights & Social Justice).

39. *See* Daniel P. Kessler, COST SHIFTING IN CALIFORNIA HOSPITALS: WHAT IS THE EFFECT ON PRIVATE PAYERS? 2 (June 2007), http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.127.1959&rep=rep1&type=pdf (suggesting that because Medicare reimbursement rates are low, hospitals shift the cost of care for Medicare patients to purchasers of private insurance) (on file with the Washington & Lee Journal of Civil Rights & Social Justice); *see also* Allen Dobson et al., *The Cost-Shift Payment 'Hydraulic': Foundation, History, and Implications*, 25 HEALTH AFF. 22, 32 (2006) ("As public payers pay less, the financial pressure on hospitals renders them less capable, not only for the uninsured and public beneficiaries, but for all those who use and expect a high level of hospital services.").

A. Overall Scope of Federal Regulatory Burden on Hospitals

Federal regulation of hospitals was relatively limited until the creation of the Medicare program in 1966.[40] Since then, federal regulation has grown exponentially.[41] In October of 2017, the AHA released a report "Regulatory Overload: Assessing the Regulatory Burden on Health Systems, Hospitals, and Post-Acute Care Providers."[42] In that report, the AHA examined 341 hospital regulatory requirements from four regulating bodies—CMS, the Office of the Inspector General, the HHS OCR, and the Office of the National Coordinator for Health Information Technology.[43]

The report found that collectively health systems, hospitals, and post-acute care providers spend nearly $39 billion a year solely on the administrative activities related to regulatory compliance.[44] More specifically, the report found "an average sized community hospital (161 beds) spends nearly $7.6 million a year on [just] administrative activities to support compliance with the reviewed federal regulations."[45] Stated another way, hospitals incurred a regulatory burden of $1,200 every time a hospital admitted a Medicare patient for inpatient care.[46] Further, that same average sized hospital dedicated fifty-nine full-time equivalent (FTE) employees to regulatory compliance, over one-quarter of which are doctors or nurses.[47] Physicians, nurses, and allied health

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40. *See* INST. OF MED., MEDICARE: A STRATEGY FOR QUALITY ASSURANCE, VOLUME II: SOURCES AND METHODS 292 (1990) (noting that hospitals participating in Medicare must meet certain Conditions of Participation (CoP) and HHS "may impose additional requirements found necessary to ensure the health and safety of Medicare beneficiaries receiving services in hospitals").

41. *See* AHA REGULATORY OVERLOAD REP., *supra* note 7, at 3 ("Health systems, hospitals, and PAC providers must comply with 629 discrete regulatory requirements across nine domains.").

42. *Id.* at 1.

43. *See id.* at 3 (characterizing these agencies as "the primary drivers of federal regulation impacting [health care] providers").

44. *Id.* at 4.

45. *Id.*

46. *Id.*

47. *Id.*

professionals are thus being pulled from patient care to instead focus on regulatory compliance.[48]

The AHA found the most costly compliance activities were related to assuring adherence to the "health quality, safety, and operational standards" set forth in the Medicare provider Conditions of Participation (CoP).[49] On average, hospitals spent $3.1 million for administrative compliance activities associated with the CoP.[50] While the figures in this AHA report indicate compliance costs are high, it is important to remember that these cost estimates are incomplete.[51] This study only examined regulatory burden imposed by four agencies and did not account for regulations form other federal agencies, such as the DOJ regulations examined in this Article.[52]

B. Federal Regulation of Medicare Hospital Providers

"Hospital participation in Medicare . . . . is voluntary."[53] However, hospitals are rarely able to opt-out of the Medicare program. All not-for-profit hospitals are required to care for Medicare beneficiaries as a condition of receiving federal tax exemption.[54] Further, Medicare is the primary health insurance plan for nearly 58 million elderly and disabled individuals in the traditional Medicare Program Part A and/or Part B programs.[55] In 2015, hospitals obtained $130 billion in Medicare reimbursement for inpatient hospital services, and an additional $64.4 billion in reimbursement for outpatient hospital services.[56] Due to the sheer size of the Medicare population and scope of services provided to

48. *See id.* at 3 ("Patients . . . are affected through less time with their caregiver, unnecessary hurdles to receiving care, and a growing regulatory morass that fuels higher health costs.").

49. *Id.* at 15.

50. *Id.*

51. *See id.* at 3 (examining the regulatory impact from only four agencies).

52. *Id.*

53. AHA UNDERPAYMENT FACT SHEET, *supra* note 38, at 1.

54. *See id.* (explaining the advantages for hospitals that participate in Medicare).

55. CMS FAST FACTS, *supra* note 5, at 1.

56. *Id.* at 3.

Medicare beneficiaries in the hospital setting, "very few hospitals can elect not to participate in Medicare . . . ."[57]

Medicare participating hospitals must comply with the Medicare CoP, a set of regulatory requirements set forth by the Secretary of HHS.[58] Hospitals must sign a written contract with HHS, known as the Medicare provider agreement, agreeing to comply with all CoP and other program requirements.[59] Hospitals may not negotiate the terms of the provider agreement with CMS.[60] The terms are set in advance by HHS and the agreement automatically renews each year without any opportunity for the hospital to negotiate terms.[61]

Hospitals' compliance with the Medicare CoP and other programmatic requirements is monitored by survey agencies.[62] Generally, these agencies are state departments of health or other agencies, or private accrediting bodies, that inspect, survey, and certify compliance on behalf of CMS and for purposes of state licensure.[63] Providers that do not comply with the terms of the Medicare provider agreement or CoP may be terminated from the program.[64] Hospitals may also be subject to other penalties

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57. AHA UNDERPAYMENT FACT SHEET, *supra* note 38, at 1.

58. *See* 42 C.F.R. § 482.1(a)(1)(i) (2018) ("Hospitals participating in Medicare must meet certain specific requirements."); *see also* AHA REGULATORY OVERLOAD REP., *supra* note 7, at 28 (explaining that CoPs are "[f]ederal requirements with which hospitals, critical access hospitals, inpatient rehabilitation facilities (IRFs) and long-term care hospitals (LTCHs) must comply in order to participate in the Medicare program").

59. *See* 42 U.S.C. § 1395c (2012) ("Any provider of services . . . shall be qualified to participate . . . and shall be eligible for payments if it files with the Secretary an agreement."); *see also* 42 C.F.R § 489.53(a)(3) (indicating that CMS may terminate a provider agreement if the provider "no longer meets the appropriate conditions of participation").

60. *See* 42 C.F.R. § 489.10 ("In order to be accepted, [the provider] must meet the conditions of participation . . . .").

61. *See id.* § 489.20 (listing "basic commitments" to which a provider must agree).

62. *See id.* § 488.10(a)(1) ("State or local survey agencies will determine whether: providers or prospective providers meet the Medicare conditions of participation or requirements . . . .").

63. *See id.* § 448.1 ("State survey agency refers to the state health agency or other appropriate state or local agency CMS uses to perform survey and review functions . . . .").

64. *See id.* § 489.53 (listing grounds for termination of the provider

including non-payment of claims or even allegations of false-claims for the submission of claims related to services provided while hospital was out of compliance.[65] Hospitals that participate with Medicare must therefore comply with all CoP and programmatic requirements to continue participation in the program and have little, if no, ability to negotiate exemptions from those requirements.[66]

The Medicare hospital CoPs require that "[t]he hospital . . . be in compliance with applicable Federal laws related to the health and safety of patients."[67] While CMS has not issued an exhaustive list of which federal laws the agency considers to be "related to the health and safety of patients," CMS has provided examples in the agency's instructions for hospital surveyors.[68] In those instructions, CMS directed surveyors to determine whether the hospital has "denied access to care for individuals with disabilities."[69] Thus, hospitals that fail to provide appropriate access to care for individuals with disabilities may be excluded from participation in the Medicare program.[70]

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agreement by CMS).

65. *See id.* § 488.406 (identifying several remedies in addition to termination of the provider agreement); *see also* Universal Health Servs., Inc. v. United States, 136 S. Ct. 1989 (2016) (holding the implied false certification theory can be a basis for liability under the False Claims Act when a defendant makes specific representations about the goods or services provided, but fails to disclose non-compliance with material statutory, regulatory, or contractual requirements making those representations misleading).

66. *See* 42 C.F.R. § 488.3 (a)(2) ("To be approved for participation in, or coverage under, the Medicare program, a prospective provider must . . . [b]e in compliance with the applicable conditions [and] certification requirements."); *see also id.* § 482.1(a)(1)(i) ("Hospitals participating in Medicare must meet certain specified requirements . . . ."); *id.* § 489.20 (listing basic conditions to which a provider must agree).

67. *Id.* § 482.11(a).

68. *See* CTRS. FOR MEDICARE & MEDICAID SERVS., STATE OPERATIONS MANUAL, APPENDIX A—SURVEY PROTOCOL, REGULATIONS AND INTERPRETIVE GUIDELINES FOR HOSPITALS at A-0021 (Dec. 29, 2017), https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf (listing Section 504 of the Rehabilitation Act of 1973) (on file with the Washington & Lee Journal of Civil Rights & Social Justice).

69. *Id.*

70. *See id.* (discussing how under Survey Procedures §482.11(a) an interview with the company determines "whether the hospital is in compliance with Federal laws related to patient health and safety" and providing the example under the

C. Medicare Payment for Hospital Services is Not Responsive to Novel Regulatory Burden

In the hospital care setting, Medicare Part A provides coverage for inpatient hospitalizations and associated services.[71] Medicare Part B Provides coverage for outpatient hospital services.[72] Hospitals participating in the Medicare Part A and Part B programs[73] are reimbursed on a prospective basis, meaning the hospitals accept a flat fee per inpatient admission or outpatient service.[74] These payments are set by law rather than through a negotiation process, as is used with private insurers. Medicare payments do not change based on the cost of services to the Medicare provider, nor in response to increased costs associated with new regulatory burdens.[75] Yet hospitals must agree to participate in the prospective payment systems in order to participate in Medicare—meaning they must agree not to demand compensation from Medicare for costs associated with regulatory

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Rehabilitation Act of 1973 § 504 a hospital may be cited for refusing disabled individuals care).

71. *See* 42 U.S.C. § 1395c (2012) ("The insurance program . . . provides basic protection against the costs of hospital, related post-hospital, home health services, and hospice care . . . ."); *see also id.* § 1395x(c) (defining the term "inpatient hospital services").

72. *See id.* § 1395k (proscribing "Supplementary Medical Insurance Benefits for Aged and Disabled," which include physician services and non-physician provider services).

73. The author acknowledges that there are a number of alternative payment strategies under the Medicare Program, including cost-based reimbursement for a small number of hospitals, Medicare managed care, and value-based purchasing. These programs are beyond the scope of this Article, which seeks to examine regulatory burden under the traditional Medicare Part A and B systems.

74. *See* 42 C.F.R. § 412.2 (2018) ("Under both the inpatient operating and inpatient capital-related prospective payment systems, hospitals are paid a predetermined amount per discharge for inpatient hospital services furnished to Medicare beneficiaries.").

75. *See Patients or Paperwork?: The Regulatory Burden Facing America's Hospitals*, AMERICAN HOSP. ASS'N, http://studyres.com/doc/12831957/patients-or-paperwork%3F---american-hospital-association (last visited on Apr. 16, 2018) ("Currently, the initial cost of implementing significant new regulations is not captured by Medicare prospective payment rate updates.") (on file with the Washington & Lee Journal of Civil Rights & Social Justice).

burden incurred in the provision of services to Medicare beneficiaries.

According to another recent AHA study, the majority of hospitals are routinely underpaid by Medicare for the costs of providing care to Medicare beneficiaries.[76] In 2016, the AHA reports that sixty-six percent of hospitals received Medicare payments that were less than the cost to the hospital of providing the associated Medicare services.[77] On average, those hospitals received payment of only eighty-eight cents for every dollar spent by the hospital caring for Medicare patients.[78] Despite this chronic underpayment, Medicare remains a crucial source of revenue for hospitals with extensive fixed overhead operating costs, and hospitals thus remain in the program despite Medicare's underpayment for some services.

1. Payments for Inpatient Services Under Medicare Part A

Prior to 1983, hospitals were reimbursed on a cost basis, meaning as hospital costs increased, hospitals were reimbursed more by the Medicare program.[79] As Medicare costs rose, Congress explored ways to control program costs.[80] In 1983 Congress passed the Social Security Act Amendments of 1983[81] which eliminated cost-based reimbursement and adopted the Inpatient Prospective Payment System (IPPS) for inpatient hospital services.[82]

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76. AHA UNDERPAYMENT FACT SHEET, *supra* note 38, at 2.

77. *Id.*

78. *Id.*

79. *See* Martin F. Grace & Jean M. Mitchell, *Regulation of Health Care Costs: The Implications of the Prospective Payment Reimbursement System*, 2 U. FLA. J.L. & PUB. POL'Y 125, 126 (1989) ("Prior to Congress' action, Medicare reimbursed hospitals on a cost basis for inpatient services rendered to its beneficiaries.").

80. *See id.* ("Congress believed that [the Medicare prospective payment system] would alleviate the inefficiency and lack of budget control associated with cost-based reimbursement.").

81. Social Security Amendments of 1983, Pub. L. No. 98-21, 97 Stat. 65 (1983) (codified at 42 U.S.C. ch. 7 (2012)) (making comprehensive changes to the Social Security benefit structure).

82. *See id.* at § 601 (discussing the "implementation of a system for including capital-related costs under a prospectively determined payment rate for inpatient

Under IPPS, hospitals are paid a predetermined flat fee for each inpatient hospital admission.[83] Hospitals are required to accept the IPPS flat fee as payment in full for the services rendered to Medicare beneficiaries.[84] The fee is determined using the "MS-DRG" system, under which patient conditions with similar clinical characteristics and treatment costs are grouped together and assigned to a specific Medicare Severity Diagnosis-Related Group (MS-DRG). [85] Each MS-DRG is then assigned a relative payment weight that reflects the average relative cost of cases in that group compared with the cost for the average Medicare case.[86] There are currently over 750 MS-DRGs, which are listed in CMS's annual notice of IPPS rates.[87]

Each hospital is then assigned a base payment rate.[88] Medicare divides the base payment rate into a labor-related share

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hospital services").

83. *See* 42 C.F.R § 412.2 (2018) ("Under both the inpatient operating and inpatient capital-related prospective payment systems, hospitals are paid a predetermined amount per discharge for inpatient hospital services furnished to Medicare beneficiaries.").

84. *See* CTRS. FOR MEDICARE & MEDICAID SERVS., ACUTE CARE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM 3 (Dec. 2016) [hereinafter CMS MLN Acute Care IPPS], https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/AcutePaymtSysfctsht.pdf ("Hospitals contract with Medicare to furnish acute hospital inpatient care and agree to accept predetermined acute IPPS rates as payment in full.") (on file with the Washington & Lee Journal of Civil Rights & Social Justice).

85. *See id.* ("Generally, you receive Medicare IPPS payment on a per discharge or per case basis . . . . Discharges are assigned to diagnosis-related groups (DRGs), a classification system that groups similar clinical conditions (diagnoses) and the procedures furnished by the hospital during the stay.").

86. *See Acute Inpatient PPS*, CTR. FOR MEDICARE & MEDICAID SERVS. (Aug. 2, 2017, 3:19 PM), https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html ("Each DRG has a payment weight assigned to it, based on the average resources used to treat Medicare patients in that DRG.") (on file with the Washington & Lee Journal of Civil Rights & Social Justice).

87. *See generally* Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2018 Rates, 82 Fed. Reg. 37990 (proposed Aug. 14, 2017) (to be codified at 42 C.F.R. § 412.13) (proposing the 2018 IPPS rates for all MS-DRGS).

88. *See id.* at 38003 ("Under these PPSs, Medicare payment for hospital inpatient operating and capital-related costs is made at predetermined, specific rates for each hospital discharge.").

and non-labor share.[89] The labor-related share allows Medicare to adjust the IPPS reimbursement rate to reflect the labor costs in the area where the hospital is located.[90] The non-labor share is a set amount except for hospitals in Alaska and Hawaii, where CMS will adjust the rate to compensate hospitals for the higher cost of living in those states.[91] The hospital's IPPS payment is calculated by multiplying the MS-DRG relative payment weight by the hospital base payment rate.[92]

The hospital's MS-DRG payment may be amended to account for specific and limited additional payments.[93] For example, hospitals that treat a high percentage of low-income patients can receive an add-on payment known as the disproportionate share hospital (DSH) adjustment.[94] Medicare-recognized teaching hospitals are eligible for direct graduate medical education (DGME) and indirect medical education (IME) adjustments, which are designed to reimburse the teaching hospital for increased costs of care associated with training medical residents.[95] Finally, in rare cases, hospitals may be entitled to "outlier payments" for particularly expensive cases.[96] Under these payments, hospitals may receive an additional payment to cover the costs of the

89. *See id.* ("The base payment rate is comprised of a standardized amount that is divided into a labor-related share and a nonlabor-related share.").

90. *See id.* ("The labor-related share is adjusted by the wage index applicable to the area where the hospital is located.").

91. *See id.* ("If the hospital is located in Alaska or Hawaii, the nonlabor-related share is adjusted by a cost-of-living adjustment factor.").

92. *See id.* (explaining that the "base payment rate is multiplied by the DRG relative weight").

93. *See id.* ("Additional payments may be made for cases that involve new technologies or medical services that have been approved for special add-on payments.").

94. *See id.* ("If the hospital treats a high percentage of certain low-income patients, it receives a percentage add-on payment applied to the DRG-adjusted base payment rate.").

95. *See id.* ("If the hospital is training residents in an approved residency program(s), it receives a percentage add-on payment for each case paid under the IPPS, known as the indirect medical education (IME) adjustment. This percentage varies, depending on the ratio of residents to beds.").

96. *See* CMS MLN Acute Care IPPS, *supra* note 84, at 12 ("To promote access to high quality inpatient care for seriously ill patients, additional payments are made for outlier or extremely costly cases.").

unusually expensive care provided to a given patient.[97] This payment is "designed to protect the hospital from large financial losses due to unusually expensive cases" and does provide reimbursement when hospitals merely spend more on a given case than the amount received under the IPPS payment.[98] Outlier payments are limited in nature, and do not provide any additional reimbursement for otherwise unfunded regulatory mandates.[99]Medicare participating hospitals thus receive the adjusted MS-DRG rate as payment in full for inpatient Medicare services, regardless of the hospital's actual costs to provide care to the specific Medicare beneficiary. The hospitals' reimbursement is not adjusted in response to novel regulatory requirements that raise the cost of care.

2. Payments for Outpatient Services Under Medicare Part B

Since August 1, 2000, Medicare has also reimbursed hospitals for outpatient services on a prospective payment system instead of using cost-based reimbursement.[100] Like under the IPPS system for inpatient services, the Outpatient Prospective Payment System (OPPS) bundles services with similar costs and resources.[101]

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97. *See id.* (explaining that outlier payments cover losses past a "fixed-loss" threshold).

98. *Acute Inpatient PPS*, *supra* note 86.

99. *See id.* (noting that the purpose of outlier payments is to shield hospitals from unusually expensive cases, which implies a limited purpose). IPPS payments are also subject to various other adjustments based on hospital characteristics (such as rural location), quality and outcome metrics (such as readmissions data and hospital acquired conditions). *See generally* CMS MLN Acute Care IPPS, *supra* note 84, at 9–14. But these adjustments are beyond the scope of this Article and do not provide reimbursement for the unfunded regulatory mandates discussed herein.

100. *See* 42 U.S.C. § 1395l(a)(2)(B) (2012) (setting reimbursement for outpatient services on a prospective basis).

101. *See* CTRS. FOR MEDICARE & MEDICAID SERVS., HOSP. OUTPATIENT PROSPECTIVE PAYMENT SYS. 4 (Jan. 2016) [hereinafter CMS MLN OPPS], https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Hospital Outpaysysfctsht.pdf (stating that CMS assigns individual services to "ambulatory payment classifications" bases on "similar clinical characteristics and similar costs") (on file with the Washington & Lee Journal of Civil Rights & Social Justice). Some services, such as certain

Specifically, outpatient procedures and services are bundled into ambulatory payment classification (APC) groups based on clinical relation and the resources needed to provide the service.[102] Unlike under IPPS, hospitals do not receive a single payment per episode of care.[103] Rather, hospitals separately bill for the individual procedures and services and may receive payment under several APCs for a single outpatient visit.[104] The hospital receives a flat fee payment for each APC that does not vary based on actual hospital costs.[105] The base rate for the APC is calculated by examining the median cost of the procedures contained within each APC.[106] As with IPPS, the hospital's actual reimbursement is adjusted to reflect differences in area labor costs.[107]

Hospitals may receive a limited number of payments in addition to the standard OPPS APC calculated reimbursement.[108] Specifically, the hospitals' final reimbursement may be increased to reflect payment for certain drugs, biologicals and devices that

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surgical procedures, blood and blood products, and certain preventative services, are paid separately instead of under the APC system, however an in-depth discussion of that payment methodology is beyond the scope of this Article. *Id.*

102. *See* 42 C.F.R. §§ 419.30–419.32 (2018) (classifying comparable outpatient procedures and weighing them based on factors including clinical relation and resources necessary to provide service).

103. *See id.* at § 419.2(a) ("Under the hospital outpatient prospective payment system, predetermined amounts are paid for designated services furnished to Medicare beneficiaries.").

104. *See id.* (setting the basis of payment for the outpatient prospective payment system). On January 1, 2015, CMS did establish certain "comprehensive APCs" to provide all-inclusive payments for certain procedures, rather than individual payments under the prior separate APC system. CMS MLN OPPS, *supra* note 101, at 4.

105. *See* CMS MLN OPPS, *supra* note 101, at 5 ("The payment rates for most separately payable medical and surgical services are determined by multiplying the prospectively established scaled relative weight for the service's clinical APC by a conversion factor (CF) to arrive at a national unadjusted payment rate for APC.").

106. *See id.* ("The scaled relative weight for an APC measures the resource requirements of the service and is based on the geometric mean cost of services in that APC.").

107. *See id.* (noting that the labor portion of the national unadjusted payment rate accounts for geographic differences in input prices).

108. *See id.* (listing payments hospitals may receive in addition to standard OPPS payments).

are separately billable under Medicare Part B.[109] Like under IPPS, hospitals are also eligible for outlier patients for outpatient services.[110] However, these outlier payments are for "exceptionally costly" cases and are not available to hospitals whose costs merely exceeded the reimbursement available under OPPS. [111]

Thus, hospitals generally receive the same OPPS prospective payment for outpatient Medicare services regardless of the hospital's actual costs to provide care to the beneficiary. Even if a regulatory requirement increases a hospital's costs with respect to services for a given Medicare beneficiary, the hospital will not receive additional payment for those increased costs from the Medicare program.

III. Regulatory Burden Under the 2016 ACA Section 1557 Regulations

The first example of regulatory burden this Article will examine is the 2016 regulations issued by the HHS OCR to implement Section 1557 of the ACA.[112] Under Section 1557 of the ACA, hospitals are required to provide translation and interpretation services for Limited English Proficiency (LEP) patients and other LEP individuals.[113] Translation and interpretation services for LEP individuals have been required for some time under a prior statute and Executive Order, but the Section 1557 regulations significantly changed the way those

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109. *See id.* (mentioning various ways hospitals may receive reimbursements in addition to standard OPPS payments).

110. *See id.* (listing outlier payments as one payment a hospital may receive in addition to standard OPPS payments). CMS also provides limited adjustments on the basis of hospital location (rural, sole community) and characteristics (cancer hospitals, children's hospitals) that are beyond the scope of this Article and do not provide reimbursement for the unfunded regulatory mandates discussed herein.

111. *See id.* (depicting on a graph payment rates for "exceptionally costly" patients); *see also* 42 C.F.R. § 419.43(d) (2018) (setting the outlier adjustment for outpatient services).

112. Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31375 (proposed May 18, 2016) (codified at 45 C.F.R. § 92).

113. *See id.* at 34410 (explaining Section 1557's prohibition on national origin discrimination).

services must be implemented and imposed more precise and costly requirements.[114]

The HHS OCR did not provide an assessment of the cost to hospitals of the 2016 Section 1557 regulations, and it is difficult to estimate those costs from other available data.[115] It is clear hospitals will incur significant additional expenses and that hospitals will not be reimbursed for those expenses by the HHS OCR itself or by the Medicare program.[116] The HHS OCR directly acknowledged in the final rule issuing the regulations that hospitals may incur additional expenses for implementation,[117] but quickly followed that no funding was provided and considerations of funding were beyond the scope of the rulemaking.[118] Instead, the agency encouraged providers to use their collective influence to lower costs and to work together to efficiently offer LEP services.[119]

A. Background and History of LEP Requirements

Hospitals have long been subject to a number of statutory and regulatory requirements related to services for LEP individuals.[120]

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114. *See id.* at 34410 ("The steps taken by a covered entity must ensure that the LEP person is given adequate information, is able to understand the services and benefits available, and is able to receive those for which he or she is eligible.").

115. *See id.* at 31458 (anticipating that the HHS regulations will add costs but noting HHS has no data as to the caseloads of affected covered entities).

116. *See infra* Part III(A. Background and History of LEP Requirements (discussing the regulatory burden under the 2016 ACA Section 1557 regulations and how those regulations increase expenses).

117. Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. at 31458 (acknowledging additional costs).

118. *See id.* at 31413 ("It is beyond the scope of this rulemaking to adopt recommendations that OCR fund qualified interpreters or direct issuers to modify medical codes and fee schedules to reimburse health care providers for their provision of language assistance services.").

119. *See id.* ("OCR encourages covered entities to work together to leverage their ability to provide language assistance services in the most cost-effective and efficient ways to meet their respective obligations under § 92.201(a) before using costs as a reason to limit language assistance services.").

120. *See, e.g.*, Civil Rights Act of 1964, Pub. L. No. 88-352, 78 Stat. 241 (1964) (codified as amended at 42 U.S.C. ch. 21 (2012)) (requiring places of public accommodation to avoid discrimination on the basis of race, color, religion, or national origin).

The foundational requirements were set forth in the Civil Rights Act of 1964.[121] Section 601 of Title VI of the Act provides that no person shall "on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance."[122] Further, Section 602 authorizes and directs federal agencies that are empowered to extend federal financial assistance to any program or activity "to effectuate the provisions of [Section 601] . . . by issuing rules, regulations, or orders of general applicability."[123]

The Department of Health, Education, and Welfare, HHS's predecessor agency, promulgated regulations pursuant to Section 602 which forbid recipients of federal funds from:

> [U]tiliz[ing] criteria or methods of administration which have the effect of subjecting individuals to discrimination because of their race, color, or national origin, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program with respect to individuals of a particular race, color, or national origin.[124]

In 1974, in the case of *Lau v. Nichols*, 414 U.S. 563 (1974),[125] the Supreme Court interpreted these Section 602 implementing regulations to prohibit conduct that has a disproportionate effect on LEP persons.[126] Specifically, the Supreme Court found that discrimination on the basis of language constituted national-origin discrimination.[127] This interpretation was reiterated by the HHS

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121. *See id.* (prohibiting discrimination in public places).

122. 42 U.S.C. § 2000d (2012).

123. *Id.* § 2000d-1.

124. Nondiscrimination Federally-Assisted Programs of the Department of Health, Education, and Welfare, Effectuation of the Title VI of the Civil Rights Act of 1964, 29 Fed. Reg. 16298, 16305 (proposed Dec. 4, 1964) (codified at 45 C.F.R. § 80.3 (2018)).

125. *See* Lau v. Nichols, 414 U.S. 563 (1974) (holding that a school systems failure to provide English language instruction violated the Civil Rights Act).

126. *See id.* at 568 (interpreting Section 602 implementing regulations as barring an educational policy that conferred fewer benefits on Chinese-speaking minorities than on the English-speaking majority).

127. *See id.* ("Where inability to speak and understand the English language excludes national origin-minority group children from effective participation in the educational program offered by a school district, the district must take

OCR[128] in a 1980 policy statement published in the Federal Register, which stated: "No person may be subjected to discrimination on the basis of national origin in health and human services programs because they have a primary language other than English."[129] Outside of this stated commitment to preventing discrimination on the basis of language, the HHS OCR issued few specific instructions for implementation.[130]

1. Executive Order 13166 and Implementing Guidance

On August 11, 2000, former President William Clinton issued Executive Order 13166, "Improving Access to Services for Persons with Limited English Proficiency."[131] The Executive Order was relatively short, and lacked detail, but it did reiterate the federal government's commitment to the Title VI requirements and required that federal agencies provide guidance to entities receiving federal funds so that those entities could improve "meaningful access" to services for LEP individuals, and thus better comply with the Title VI requirements.[132]

In compliance with the Executive Order, the HHS OCR published final guidance governing health care providers on August 8, 2003.[133] In that guidance, the HHS OCR went on to

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affirmative steps to rectify the language deficiency in order to open its instructional program to these students." (citations omitted)).

128. The OCR is the HHS department specifically charged with "enforce[ing] laws against discrimination based on race, color, national origin, disability, age, sex, and religion by certain health care and human services." *Civil Rights for Individuals and Advocates*, U.S. DEP'T HEALTH & HUM. SERVS., https://www.hhs.gov/civil-rights/for-individuals/index.html (last visited Apr. 16, 2018) (on file with the Washington & Lee Journal of Civil Rights & Social Justice).

129. HHS Nondiscrimination on the Basis of Race, Color, or National Origin Under Programs Receiving Federal Financial Assistance Through the Department of Health and Human Services, 45 Fed. Reg. 82972, 82972 (proposed Dec. 17, 1980) (codified as 45 C.F.R. pt. 80).

130. *See, e.g.*, *id.* (prohibiting discrimination in general terms without setting specific requirements).

131. Exec. Order No. 13,166, 65 Fed. Reg. 50121 (Aug. 11, 2000).

132. *See id.* ("Each Federal agency shall also work to ensure that recipients of Federal financial assistance (recipients) provide meaningful access to their LEP applicants and beneficiaries.").

133. Guidance to Federal Financial Assistance Recipients Regarding Title VI

describe four factors health care entities should use to assess what assistance is necessary to ensure meaningful access to services for LEP persons.[134] Specifically, the HHS OCR directed entities to consider:

> (1) The number or proportion of LEP persons eligible to be served or likely to be encountered by the program or grantee; (2) the frequency with which LEP individuals come in contact with the program; (3) the nature and importance of the program, activity, or service provided by the program to people's lives; and (4) the resources available to the grantee/recipient and costs.[135]

This four-factor approach was intended to be flexible for providers and avoid undue burden for smaller entities.[136] The guidance explained that if a provider determines LEP assistance is needed based on the four-factor analysis, the providers could provide services in two primary ways: Written translation and oral interpretation services.[137] The guidance provided flexibility in the way those translation and interpretation services were provided.[138]

2. Guidance Related to Written Translation Services

Under the Executive Order 13166 implementing guidance, hospitals were left with a great deal of flexibility in determining

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Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons, 68 Fed. Reg. 47311 (Aug. 8, 2003) [hereinafter OCR E.O. 13166 Guidance] (issuing guidance pursuant to Executive Order 13166).

134. *See id.* at 47314 ("While designed to be a flexible and fact-dependent standard, the starting point is an individualized assessment that balances the following four factors . . . .").

135. *Id.*

136. *See id.* ("[T]he intent of this guidance is to suggest a balance that ensures meaningful access by LEP persons to critical services while not imposing undue burdens on small business, small local governments, or small nonprofits.").

137. *See id.* at 47315 ("Recipients have two main ways to provide language services: Oral interpretation either in person or via telephone interpretation service . . . and written translation . . . .").

138. *See id.* at 47316 ("Regardless of the type of language service provided, quality and accuracy of those services is critical to avoid serious consequences to the LEP person and to the recipient. Recipients have substantial flexibility in determining the appropriate mix.").

what documents should be translated, to what extent, and by whom.[139] The HHS OCR directed that the extent of the provider's "obligation to provide written translations for documents should be determined on a case-by-case basis, looking at the totality of the circumstances in light of the four-factor analysis." [140] The HHS OCR further suggested that, because translation is a one-time, up-front expense, the cost of translation should be amortized over the likely lifespan of the document when applying the four-factor analysis.[141]

After conducting the four-factor analysis, providers "*may* determine that they need to translate vital written materials into the language of each frequently-encountered LEP group eligible to be served or likely to be affected by the [provider's] program" in order to have an effective LEP service plan.[142] The HHS OCR explained that vital documents may include consent and complaint forms; intake forms with the potential for important consequences; written notices alerting individuals to important rights; and notices advising LEP individuals of the existence of free language assistance.[143]

The HHS OCR also noted that the translation could range from translating the entire document to translating a short description of the document, depending on need.[144] Further, the HHS OCR explained that it did not expect providers to translate services into a set number of languages.[145] The HHS OCR instructed providers to examine which languages are frequently encountered by the provider. However, the HHS OCR also noted that in some large cities providers might encounter dozens or even

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139. *See id.* (providing hospitals with flexibility to determine the correct "mix" of language assistance services).

140. *Id.* at 47319.

141. *See id.* (suggesting an amortization schedule for translation costs).

142. *Id.*

143. *See id.* at 47319 (listing vital documents for purposes of translations services).

144. *See id.* at 47314 ("One factor in determining what language services recipients should provide is the number or proportion of LEP persons from a particular language group served or encountered in the eligible service population.").

145. *See id.* at 47319 (setting out expectations for translations).

over a hundred different languages, yet it was unrealistic to expect translation into all of those languages.[146]

The HHS OCR instructed that providers should use only "competent" translators, yet clarified a "[translator] certification or accreditation is not always possible or necessary."[147] Rather, a translator is "competent" if he or she understands "the expected reading level of the audience and, where appropriate, has fundamental knowledge about the target language group's vocabulary and phraseology."[148] The HHS OCR offered that providers may be able to utilize "community organizations to help consider whether a document is written at a good level for the audience."[149]

3. Guidance Related to Oral Interpretation Services

In the Executive Order 13166 implementing guidance, the HHS OCR again directed providers to use the four-factor analysis to determine what oral interpretation services are required.[150] Specifically, the HHS OCR clarified that oral interpretation could range from "on-site interpreters for critical services provided to a high volume of LEP persons, to access through commercially–available telephonic interpretation services."[151] Further, the HHS OCR noted that "[i]n some cases, language services should be made available on an expedited basis while in others the LEP individual may be referred to another office of the provider, or even to another provider, for language assistance."[152]

The HHS OCR offered providers discretion in selecting an appropriate interpreter.[153] The HHS OCR cautioned that

146. *See id.* (taking a pragmatic approach to selecting languages for translation).

147. *Id.* at 43716. The HHS OCR further suggested that providers could ensure competent translations by having a "second, independent translator" check the work of the primary translator. *Id.*

148. *Id.*

149. *Id.* at 47316–17.

150. *See id.* at 47315 (providing a guidepost for healthcare providers).

151. *Id.*

152. *Id.*

153. *See id.* at 47316 (stating that providers "have substantial flexibility in

interpreters should be "competent," which required "more than self-identification as bilingual."[154] The HHS OCR explained, competency requires that the interpreter "demonstrate proficiency in and ability to communicate information accurately in both English and the other language and identify and employ the appropriate mode of interpreting (e.g. consecutive, simultaneous, summarization, or sight translation)."[155] Further, the interpreter should have knowledge in both languages of any necessary specialized terms or concepts used by the provider and any particularized vocabulary and phraseology used by the LEP individual.[156] The interpreter must understand and follow the provider's confidentiality and impartiality rules and understand his or her role as an interpreter without deviating from his or her role as an interpreter without deviating into other roles, such as counselor or advisor.[157] The HHS OCR clarified that such requirements may be met by a lay interpreter and stated that interpreters are not required to have formal certification.[158]

Given the relatively flexible competency, confidentiality, and impartiality rules set forth in the guidance, the HHS OCR went on to explain that providers had many options when selecting appropriate interpreter.[159] For example, providers could hire bilingual staff who are competent to communicate directly with LEP persons in their language.[160] Providers could also hire staff interpreters "where there is a frequent need for interpreting services."[161] Further, providers may find contract interpreters to be a more cost effective option if they do not have regular need for

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determining the appropriate mix" of language services).

154. *Id.*

155. *Id.*

156. *See id.* (describing what is important for competent interpretation).

157. *See id.* (setting the outer limits for interpreters).

158. *See id.* ("Where individual rights depend on precise, complete, and accurate interpretation or translations, particularly in the context of administrative proceedings, the use of certified interpreters is strongly encouraged.").

159. *See id.* at 47316–17 (pointing out several language assistance options for providers).

160. *See id.* at 47317 ("When particular languages are encountered often, hiring bilingual staff offers one of the best, and often most economical, options.").

161. *Id.*

services.[162] Providers could also use telephone interpreter lines, though the HHS OCR cautioned "nuances in language and non-verbal communication can often assist an interpreter and cannot be recognized over the phone.[163] The HHS OCR offered that video teleconferencing, if available, may sometimes help to resolve this issue where necessary.[164]

Finally, the HHS OCR offered several mechanisms for hospitals to obtain free interpretation services.[165] First, the HHS OCR suggested that providers look into using "community volunteers," provided those individuals are competent in interpreting.[166] The HHS OCR also noted family members and friends could be used, so long as the provider offers another interpreter free of charge and the LEP still desired to use his or her family member or friend instead.[167] The HHS OCR directed providers to respect an LEP individual's choice to use a family member or friend as an interpreter, so long as the provider considered issues of competency, appropriateness, potential conflicts of interests, and confidentiality.[168] If concerns in those areas arise, providers should make another appropriate interpreter available in lieu of the family member or friend to supplement the companion's services.[169] The HHS OCR also urged providers to honor individuals' choices to use minors as interpreters, but did caution that, "additional issues of competency, confidentiality, or conflict of interest the choice involves using minor children as interpreters."[170] Thus, providers

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162. *Id.*

163. *See id.* ("It may be as simple as being prepared to use one of the commercially available telephonic interpretation services to obtain immediate interpreter services.").

164. *Id.*

165. *See id.* (listing cost-free alternatives for interpretation services).

166. *See id.* ("[U]se of [provider]-coordinated volunteers, working with . . . community-based organizations may provide a cost effective supplemental language assistance strategy . . . .").

167. *Id.*

168. *See id.* at 47318 (signaling concerns associated with using family members and friends as interpreters).

169. *See id.* (discussing the reasonable steps that may need to be taken if an informal interpreter is inappropriate).

170. *Id.*

had a lot of flexibility and many ways to access free interpretation services with the patient's permission.

4. Cost Estimates for Hospital Implementation of Executive Order 13166

After Executive Order 13166 was issued, the Office of Management and Budget (OMB) issued a report assessing the costs of implementing the Executive Order.[171] While the report left some important holes in the cost estimate analysis for Medicare associated care, it is an important tool for assessing the anticipated costs of hospital compliance. Specifically, the report only examined oral interpretation services without providing information on written translations.[172] Further, the report included cost estimates for all hospitals, regardless of the payer.[173] This is important because some payers, including certain state Medicaid programs and private insurers, may reimburse providers for interpretation costs.[174] Medicare, other state Medicaid programs, and many private insurers, do not.[175] Despite these shortcomings, the report does provide a helpful estimate of the scale of the burden placed on hospital providers under the Executive Order.[176]

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171. *See* OFFICE OF MGMT. & BUDGET, REPORT TO CONGRESS. ASSESSMENT OF THE TOTAL BENEFITS & COSTS OF IMPLEMENTING EXEC. ORDER NO. 13166: IMPROVING ACCESS TO SERV. FOR PERS. WITH LTD. ENGLISH PROFICIENCY (Mar. 14, 2002) [hereinafter OMB E.O. 13166 COST REPORT] (analyzing the consequences of Executive Order No. 13166 on healthcare providers).

172. *See id.* at 45 (noting that the report "does not cover fixed-cost translations of forms and hospital signs").

173. *See id.* at 46 (establishing the parameters of the assessment report).

174. *See Translation and Interpretation Services*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/financing-and-reimbursement/admin-claiming/translation/index.html (last visited Apr. 16, 2018) (describing Medicaid financing and reimbursement procedures for translation services) (on file with the Washington & Lee Journal of Civil Rights & Social Justice).

175. *See* OMB E.O. 13166 COST REPORT, *supra* note 171, at 46 ("In many cases, the costs fall on the individual provider, clinic, or hospital, with little or no reimbursement from insurance providers or government programs.").

176. *See id.* at 59 ("[T]his report uses data and assumptions about different types of language-assistance services that could be provided to LEP individuals in a variety of contexts to assess the general benefits and costs of language assistance services.").

The OMB report estimated the cost of interpretation services by looking at the number of visits to hospital emergency departments, outpatient departments, and inpatient admissions by LEP individuals needing interpretation services in the year 1999.[177] As detailed below, the report presumed that a large percentage of interpretation services could be provided at no cost to the hospital.[178] Even with these presumptions, the annual costs for interpretation services were substantial.[179]

In the emergency department context, the OMB estimated that hospitals would need to obtain 704,000 hours of LEP interpretation services.[180] However, the OMB estimated that a full seventy percent of those interactions would be conducted at no cost to the hospital.[181] Specifically, the OMB estimated that family members and friends could facilitate ten percent of interactions; free volunteer interpreters another ten percent; and another fifty percent of interactions would be handled by bilingual medical staff.[182] The OMB found that hospitals would incur costs when ten percent of interactions were handled by staff interpreters at a cost of $26.00 per hour; fifteen percent by a language bank at a cost of $20.00 per hour; and five percent of interactions via a language line at a cost of $132.00 per hour.[183] This led to a total anticipated cost of $8.5 million per year for interpretation in the emergency department setting.[184]

Similarly, in the outpatient hospital setting, the OMB estimated that hospitals would need to obtain 950,000 hours of

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177. *Id.* at 45–48.

178. *See id.* at 47 ("Providers will not incur additional costs based on the interactions of LEP individuals with trained medical staff that are (at least functionally) bilingual . . . .").

179. *See id.* at 56 ("Using the data from our healthcare sector discussion, we estimate that healthcare providers could spend up to $267.6 million on language services for approximately 66.1 million ER visits, inpatient hospital visits, outpatient physician visits, and dental visits by LEP persons.").

180. *Id.* at 48.

181. *See id.* at 48 (identifying the number of Emergency Room interactions facilitated through bilingual medical staff, volunteer interpreters, and family members and friends).

182. *Id.* at 48.

183. *Id.* at 48.

184. *Id.* at 48.

interpretation services.[185] The OMB again estimated that ten percent of interactions would be provided by family members and friends; ten percent would be provided by free volunteer interpreters; and another fifty percent of interactions would be handled by bilingual medical staff.[186] The OMB also again estimated ten percent of the remaining services would be provided by staff interpreters at a cost of $26.00 per hour; fifteen percent by a language bank at a cost of $20.00 per hour.[187] This led the OMB to conclude hospitals would incur total outpatient interpretation costs of $12.4 million per year.[188]

Finally, in the inpatient hospital setting, the OMB estimated hospitals would need to obtain 6.41 million hours of LEP interpretation services.[189] Again, the OMB estimated a large percentage would be provided free of charge, with ten percent of interactions provided by family members and friends; ten percent of interactions provided by free volunteer interpreters; and another fifty percent of interactions handled by bilingual medical staff.[190] The OMB again found that ten percent of the remaining services would be provided by staff interpreters at a cost of $26.00 per hour; fifteen percent by a language bank at a cost of $20.00 per hour; and five percent of interactions via a language line at a cost of $132.00 per hour.[191] This led to a total anticipated cost of $78.2 million per year.[192]

Thus, even presuming up to seventy percent of all LEP interpretation would be provided at no additional costs to hospitals, the OMB concluded hospitals could anticipate approximately $99.2 million dollars in LEP interpretation costs for a single year of services under the Executive Order.

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185. *See id.* at 51 (recognizing potential costs associated with outpatient visits to hospitals).

186. *See id.* at 51 (providing ten percent of interactions for family members and friends, ten percent of interactions for free volunteer interpreters, and fifty percent of interactions for bilingual staff).

187. *Id.* at 51.

188. *Id.* at 51.

189. *Id.* at 49.

190. *Id.* at 49.

191. *Id.* at 49.

192. *Id.* at 49.

B. Significant Changes to LEP Requirements Under the 2016 HHS OCR Regulations Implementing Section 1557 of the ACA

When the Patient Protection and Affordable Care Act was passed in 2010, it included substantial changes to the requirements to provide written translation and oral interpretation services to LEP individuals.[193] Like Title VI of the Civil Rights Act and Executive Order 13166, Section 1557 of the ACA also prohibited health care providers that receive federal funds from discriminating against patients on the basis of national origin.[194] Providers were also required to continue to provide language services to LEP individuals free of charge to ensure meaningful access to health care services.[195] Further, providers similarly retained flexibility in deciding when services are required to obtain meaningful access based on the type of communication needed.[196] Unlike earlier requirements, the 2016 Section 1557 regulations severely limited providers' discretion in how to provide meaningful access to LEP individuals in order to avoid discrimination and imposed new requirements on providers with respect to translation and interpretation services.[197]

1. Expanded Scope of Services

Prior to the implementation of Section 1557, hospitals generally presumed that translation and interpretation

193. *See* Patient Protection and Affordable Care Act, Pub. L. No. 111–148, 124 Stat. 119 (2010) [hereinafter ACA].

194. *See* Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31386 (proposed May 18, 2016) (codified at 45 C.F.R. § 92) ("We proposed that the term 'individual with limited English proficiency' codify the Department's longstanding definition reflected in the guidance interpreting Title VI's prohibition of national origin discrimination . . . .").

195. Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. at 31395.

196. *See id.* at 31386 (explaining LEP assistance services may include "(1) oral language; (2) written translation of documents and Web sites; and (3) taglines" and noting providers have the "flexibility to provide language assistance services in-house or through commercially available options").

197. *See id.* (tying the nondiscrimination requirements of 2016 Section 1557 Fed. Reg. Notice to those of the Civil Rights Restoration Act).

obligations only applied to patients.[198] Under the 2016 Section 1557 regulations, providers must "take reasonable steps to provide meaningful access to each individual with limited English proficiency eligible to be served *or likely to be encountered* in its health programs and activities."[199] This statement has been interpreted to mean the duty to provide qualified medical interpreters is not confined to LEP patients, but also extends to family members, spouses, or same sex partners of LEP patients who are themselves LEP.[200] This expansion to companions of LEP individuals is likely to substantially increases the volume of LEP services provided by hospitals.

2. Increased Translator Qualification Requirements and Novel LEP Rights Notice Provisions

The 2016 Section 1557 regulations changed the requirements for translation services in two important ways. First, the regulations set new limits on which individuals could provide translation services.[201] Under the 2016 regulations, health care providers must now use "qualified" translators in written translation services.[202] This is a change from the prior language

198. *See* David B. Hunt, *Important New Language Access Legal Developments*, CME LEARNING (May 1, 2016), https://www.cmelearning.com/new-2016-aca-rules-significantly-affect-the-law-of-language-access/ (describing increased scope of services as change from prior law) (on file with the Washington & Lee Journal of Civil Rights & Social Justice).

199. 45 C.F.R § 92.201(a) (2018) (emphasis added).

200. *See Section 1557: Frequently Asked Questions*, HHS.GOV [hereinafter Section 1557: FAQ], https://www.hhs.gov/civil-rights/for-individuals/section-1557/1557faqs/index.html (last visited Apr. 16, 2018) (providing explanations to common questions related to Section 1557 Implementing Regulations) (on file with the Washington & Lee Journal of Civil Rights & Social Justice); *see also* Hunt, *supra* note 198 ("[T]he duty to provide qualified medical interpreters is not confined to LEP patients but also extends to family members, spouses or same-sex partners of LEP patients who are themselves LEP.").

201. *See* 45 C.F.R. § 92.4 (setting the operative definitions for new ACA regulations).

202. *See id.* (describing a qualified interpreter for the purposes of the new ACA regulations).

requiring "competent" translators.[203] A "qualified" translator is one who:

> (1) Adheres to generally accepted translator ethics principles, including client confidentiality; (2) has demonstrated proficiency in writing and understanding both written English and at least one other written non-English language; and (3) is able to translate effectively, accurately, and impartially to and from such language(s) and English, using any necessary specialized vocabulary, terminology and phraseology.204

Translators do not need to be certified to meet the more stringent "qualified translator" requirements.[205]

Under the prior Executive Order 13166 guidance, providers were only required to use "competent" translators.[206] A translator is "competent" when he or she understands "the expected reading level of the audience and, where appropriate, has fundamental knowledge about the target language group's vocabulary and phraseology."[207] Thus, the Section 1557 qualification goes beyond the prior competency standard required under the Executive Order and will likely limit the individuals who can provide compliant translation services.

Second, the 2016 Section 1557 regulations established new notice written requirements related to translation and interpretation services.[208] Specifically, under the regulations, providers are required to publish notices regarding LEP individual's rights related to language assistance services and "taglines" notifying LEP individuals where they can obtain additional information about their rights.[209] Providers must post the following notice provisions in English and also include the notice in English in all significant publications:

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203. OCR E.O. 13166 Guidance, *supra* note 133, at 47316.

204. 45 C.F.R. § 92.4.

205. *See id.* (detailing general definitions under the HHS regulations).

206. OCR E.O. 13166 Guidance, *supra* note 133, at 47316.

207. *Id.*

208. *See* 45 C.F.R. § 92.8 (2018) (explaining that the HHS covered entity notice requirements to "beneficiaries, enrollees, applicants, and members of the public").

209. *See id.* (discussing the HHS covered entity notice requirements and tagline requirements).

> (1) The covered entity does not discriminate on the basis of race, color, national origin, sex, age, or disability in its health programs and activities;
>
> (2) The covered entity provides appropriate auxiliary aids and services, including qualified interpreters for individuals with disabilities and information in alternate formats, free of charge and in a timely manner, when such aids and services are necessary to ensure an equal opportunity to participate to individuals with disabilities;
>
> (3) The covered entity provides language assistance services, including translated documents and oral interpretation, free of charge and in a timely manner, when such services are necessary to provide meaningful access to individuals with limited English proficiency;
>
> (4) How to obtain the aids and services [explained above];
>
> (5) An identification of, and contact information for, the responsible employee designated [to coordinate aids and services], if applicable;
>
> (6) The availability of the grievance procedure and how to file a grievance . . . ; and,
>
> (7) How to file a discrimination complaint with OCR in the Department.[210]

Additionally, providers must also post and, include in all significant publications, "taglines" in the top fifteen languages spoken by individuals within the state.[211] "Taglines" are "short statements written in non–English languages that indicate the availability of language assistance services free of charge."[212] A sample tagline was provided within the regulation and reads as follows:

> ATTENTION: If you speak [insert language], language assistance services, free of charge, are available to you. Call 1–xxx-xxx-xxxx (TTY: 1–xxx-xxx-xxxx).[213]

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210. *Id.* § 92.8(a).
211. *Id.* § 92.8(d)(1).
212. *Id.* § 92.4.
213. *Id.* app. § 92 B.

Providers do have discretion to determine which publications are significant under the rule, but must now assess all publications to determine if the notices are required.[214] The HHS OCR has instructed that the agency considers communications significant when they include applications to participate in, or receive benefits or services from, a provider, as well as written correspondence related to an individual's rights, benefits, or services.[215] In contrast, the HHS OCR generally does not view outreach, education and marketing materials to be significant.[216] Further, HHS included an exception for small-sized significant publications such as postcards, pamphlets, or tri-fold brochures.[217] For those documents, the provider need only publish a nondiscrimination statement in English and taglines in the top two languages spoken by LEP individuals within the state.[218]

3.Increased Interpreter Qualification Requirements

The 2016 Section 1557 implementing regulations also placed significant new limitations on interpretation services.[219] First, the 2016 regulations severely limited the use of free family members or friends to provide translation services. Under Executive Order 13166, the HHS OCR directed providers to respect an LEP

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214. Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31402 (proposed May 18, 2016) (codified at 45 C.F.R. § 92) (explaining the modified notice requirement allows providers "to exclude publications . . . that are small in size from the requirement to post all of the content specified in § 92.8; instead, covered entities will be required to post only a shorter nondiscrimination statement in such communications and publications").

215. Section 1557: FAQ, *supra* note 200.

216. *See* Section 1557: FAQ, *supra* note 200 ("OCR would not generally view all of an entity's outreach, education, and marketing materials to be categorized as 'significant.'").

217. *See* 45 C.F.R. § 92.8(f)(1)(i) (2018) (discussing how each entity is required to provide notice to beneficiaries, enrollees, applicants, and members of the public via "significant publications and significant communications that are small-sized, such as postcards and tri-fold brochures").

218. *See id.* § 92.8(d)(1) ("As described in paragraph (f)(1) of this section, post taglines in at least the top 15 languages spoken by individuals with limited English proficiency of the relevant State or States.").

219. *See id.* § 92.201 (detailing specific requirements for interpreter and translation services).

individual's choice to use a family member or friend as a translator, so long as the provider considers issues of competency, appropriateness, potential conflicts of interest and confidentiality.[220]

Under the new Section 1557 regulations, providers may not use accompanying adults, including family members or friends, as interpreters unless: 1) There is an emergency involving imminent threat to the safety or welfare of an individual or the public and there is no qualified interpreter for the LEP individual immediately available; or 2) the LEP individual specifically requests the accompanying adult interpret or facilitate communication, the accompanying adult agrees, and the provider finds such assistance is appropriate under the circumstances.[221] Further, providers may never request or require that an LEP individual provide his or her own interpreter.[222]

Additionally, under the Section 1557 regulations, providers may never use minor children as interpreters, even if requested by the LEP individual, except in the rare instance that there is an emergency involving an imminent threat to the safety or welfare of an individual or the public and where there is no qualified interpreter immediately available.[223] This is again a departure from the Executive Order 13166 guidance, in which the HHS OCR urged providers to honor individual's choices to use minors as interpreters, and simply cautioned that "additional issues of competency, confidentiality, or conflict of interest when the choice involves using minor children as interpreters."[224]

Second, the Section 1557 regulations no longer mention or suggest the use of community volunteers to provide interpretation

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220. *See* OCR E.O. 13166 Guidance, *supra* note 133, at 47318 (allowing LEP individuals to choose a translator so long as the translator meets certain criteria under the guidance).

221. *See* 45 C.F.R. § 92.201(e) (restricting the use of certain persons to interpret or facilitate communication).

222. *See id.* § 92.201(e)(1) ("[A covered entity shall not] require an individual with limited English proficiency to provide his or her own interpreter.").

223. *See id.* § 92.201(e)(3) ("[A covered entity shall not] rely on a minor child to interpret or facilitate communication.").

224. OCR E.O. 13166 Guidance, *supra* note 133, at 47317.

services, thus eliminating another free source of translation permitted and contemplated under Executive Order 13166.[225]

Finally, the regulations also imposed more stringent standards for which bilingual and multilingual staff providers may use to provide interpretation services.[226] Bilingual and multilingual staff must now be "qualified,"[227] meaning the staff member must be:

> Designated by the covered entity to provide oral language assistance as part of the individual's current, assigned job responsibilities and [have] demonstrated to the covered entity that he or she:
>
> (1) Is proficient in speaking and understanding both spoken English and at least one other spoken language, including any necessary specialized vocabulary, terminology and phraseology; and,
>
> (2) is able to effectively, accurately, and impartially communicate directly with individuals with limited English proficiency in their primary languages.228

The HHS OCR clarified that the new definition of "qualified bilingual/multilingual staff" was designed to clarify the knowledge, skills and abilities that a staff member must demonstrate for a covered entity to designate the staff member as effective to provide oral language assistance.[229] Based on these new requirements, providers must now assess staff members qualifications and formally designate individual staff members as qualified interpreters.

4. Novel Video Remote Interpreting Requirements

The 2016 Section 1557 implementing regulations include new rules regarding the use of video remote interpreting services.[230]

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225. *Id.*

226. *See* 45 C.F.R. § 92.201(e) (2018) (detailing restricted use of certain persons to interpret or facilitate communication).

227. *Id.* § 92.201(d).

228. *Id.* § 92.4.

229. *See id.* § 92.4(e)(4) (defining "qualified bilingual/multilingual").

230. *Id.* § 92.201(f).

Under the regulations, providers can use video remote interpreting services, but only if the services provide:

> (1) Real-time, full-motion video and audio over a dedicated high-speed, wide-bandwidth video connection or wireless connection that delivers high-quality video images that do not produce lags, choppy, blurry, or grainy images, or irregular pauses in communication;
>
> (2) A sharply delineated image that is large enough to display the interpreter's face and the participating individual's face regardless of the individual's body position;
>
> (3) A clear, audible transmission of voices; and,
>
> (4) Adequate training to users of the technology and other involved individuals so that they may quickly and efficiently set up and operate the video remote interpreting.[231]
>
> These rules were intended to address concerns that video remote interpreting technologies may result in less comprehensible communication for LEP individuals.[232]

C. Increased Costs to Hospitals Imposed by the 2016 Section 1557 Regulations

Medicare does not reimburse hospitals for language services provided to Medicare beneficiaries.[233] Further, hospitals may not seek reimbursement from patients or other individuals requiring services.[234] Instead services must be provided free of charge.[235]

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231. *Id.*

232. Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31418 (proposed May 18, 2016) (codified at 45 C.F.R. § 92) ("These standards are designed to achieve parity with the regulation in the disability rights context regarding video remote interpreting technologies.").

233. *See Translation and Interpretation Services*, *supra* note 174 (explaining that language interpretation services need not be reimbursed).

234. Section 1557: FAQ, *supra* note 200. This is true even if the hospital hired an interpreter in anticipation of need for an appointment or admission and the patient failed to show. *See id.* ("[U]nder Section 1557 and its implementing regulation, an individual cannot be charged for oral interpretation services, even if such services were scheduled for an appointment that an individual with limited English proficiency missed.").

235. *Id.*

Despite the documented changes implemented in the 2016 Section 1557 regulations, HHS did not provide comprehensive cost estimates for the new regulatory requirements.[236] Further, HHS did not provide any additional funding to providers to pay for translation or interpretation services.[237] HHS explained the lack of funding, stating:

> This rule implements the provisions of Section 1557. In most respects, the rule clarifies existing obligations under existing authorities, and we have noted in the cost analysis that we do not expect that covered entities will incur costs related to the clarification of those existing obligations in the final rule. As the HHS LEP Guidance and regulation implementing Title VI indicate, recipients are already required to take reasonable steps to ensure meaningful access to their programs and activities by persons with limited English proficiency. We note that the additional provisions related to serving individuals with limited English proficiency in the final rule may create some additional costs but will also create substantial benefits to patients and providers by improving access to quality care.[238]

This analysis from HHS is unsatisfactory. First, as HHS acknowledged, providers can expect to incur additional costs associated with the new restrictions on the provision of translation and interpretation services.[239] However, "some additional costs"[240] minimizes the potential impact, even using the HHS OCR's own prior calculations of costs and outdated cost data.[241] Second, instead of specifically identifying and absorbing the costs associated with improved services for LEP individuals, the HHS OCR put the onus on the provider community to pay for the novel

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236. *Id.*

237. *See id.* ("There is no dedicated funding available to covered entities to implement the nondiscrimination provisions of the Title VI and Section 1557 that prohibit discrimination on the basis of national origin and require covered entities to take reasonable steps to provide meaningful access to individuals with limited English proficiency.").

238. Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31458 (proposed May 18, 2016) (codified at 45 C.F.R. § 92) (emphasis added).

239. *Id.* at 31458.

240. *Id.*

241. *Id.* at 31454.

Section 1557 regulations.[242] HHS openly acknowledged it was passing the compliance burden onto the provider community, stating:

> It is beyond the scope of this rulemaking to adopt recommendations that OCR fund qualified interpreters or direct insurers to modify medical codes and fee schedules to reimburse health care providers for their provision of language assistance services. OCR encourages covered entities to work together to leverage their ability to provide language assistance services in the most cost-effective and efficient ways to meet their respective obligations under § 92.201(a) before using costs as a reason to limit language assistance services. OCR also encourages professional associations and organizations to consider what role they can play in helping their members meet the requirements of § 92.201; we provided similar encouragement in the HIPAA Privacy Rule.[243]

Simply touting the benefits of services and encouraging providers to band together to lower costs is insufficient. As detailed below, hospitals are likely to incur significant additional costs, with no corresponding payment offset from the regulatory agency.

1. Costs Related to New Translation Regulations

The HHS OCR failed to provide cost estimates for the more stringent translator qualification requirements imposed by the 2016 Section 1557 regulations, making it difficult to assess the costs associated with these new requirements.[244] The Section 1557 Notice of Final Rule did include estimated costs for the notice and tagline provisions required under 45 C.F.R. § 92.8.[245] Yet, even these estimates are incomplete and insufficient.

The HHS OCR estimated it would take an average of seventeen minutes to download and post the required notice provisions and an additional seventeen minutes of administrative time to download taglines in the top fifteen languages in the

242. *Id.*

243. *Id.* at 31413.

244. *See id.* at 31394 (describing the estimated costs to be "minimal").

245. *Id.* at 31394.

states.[246] The HHS OCR calculated this means an average of thirty-four minutes at each of 405,534 affected hospitals impacted by the rule.[247] With a presumed clerical salary of $15.52 per hour, the OMB estimated the total cost would be approximately $7.1 million with appropriate adjustments.[248] Thus, while the cost per provider was relatively nominal, the aggregate costs across the provider community were substantial.

Further, this $7.1 million burden is likely well below actual provider cost. It is important to note that the OMB only included burden for the initial download and posting of required notice and taglines.[249] The OMB did not include the anticipated burden for assessing each provider document to determine whether the disseminated document is a "significant communication" and, if so, to add the notice and taglines to that document.[250]

2. Costs Related to New Interpretation Regulations

In 2002 when the OMB assessed the potential cost implications of Executive Order 13166, the OMB anticipated hospitals could incur annual costs of $8.6 million for emergency department LEP interpretation services, $12.4 million for outpatient LEP services, and $78.2 million for inpatient LEP services.[251] In making those calculations, the OMB assumed that seventy percent of all interpretation services would be provided at no cost to hospitals.[252] Specifically, the OMB presumed ten percent of interpretation would be performed by family members and friends, ten percent by community volunteers, and fifty percent by

246. *See id.* at 31443 ("OCR estimates that the burden for responding to the proposed notice requirement is an average of 17 minutes to download and post the notice.").

247. *Id.*

248. *Id.*

249. *See id.* at 31453 ("We estimate that the combined costs of printing and distributing notices, nondiscrimination statements, and taglines will be $7.1 million for entities and $70,400 for the Federal government.").

250. *Id.* at 31401.

251. OMB E.O. 13166 COST REPORT, *supra* note 171, at 48–49, 51.

252. *Id.*

bilingual staff.[253] These "free" services accounted for annual value of $146.3 million.[254]

Under the 2016 Section 1557 regulations, providers are restricted from accessing these "free services"[255] for interpretation. Specifically, the Section 1557 regulations significantly limit hospitals' ability to use adult or minor family members or friends in interpretation services.[256] These new restrictions will preclude hospitals from obtaining the OMB anticipated ten percent of the interpretation services for free from free family and friends. Second, the Section 1557 regulations no longer mention community volunteers as a viable source of interpretation services.[257] While it may be possible for hospital providers to obtain some assistance from community volunteers, it seems unlikely providers will find enough willing community-based "qualified interpreters"[258] to provide ten percent of all necessary interpretation services for free, as the OMB report contemplated.[259]

Finally, the 2016 regulations require a more rigorous and formalized process of designating bilingual and multilingual staff as qualified interpreters.[260] Hospitals are likely to incur costs associated with the review of staff qualifications and the designation process. This process may also reduce the number of staff able to serve as interpreters under the new regulations. While the HHS OCR did not provide any estimates of the number of staff members that may now be precluded from interpreting under the more stringent standard, with the OMB estimating that fifty percent of anticipated interpretation services could be provided for

253. *Id.*

254. *See id.* (totaling the $12.6 million for emergency department services, $16.8 million for outpatient services, and $116.9 for inpatient services).

255. 45 C.F.R. § 92.201(e) (2018).

256. *See id.* (imposing strict standards to "account for issues of competency, confidentiality, privacy, and conflict of interest that arise as a result of relying on informal (or ad hoc) interpreters").

257. *Id.*

258. *Id.* § 92.4(1).

259. OMB E.O. 13166 COST REPORT, *supra* note 171, at 48–49, 51.

260. *See* 45 C.F.R. § 92.201(e) (2018) (describing regulatory changes related to qualifying bilingual and multilingual staff as interpreters).

free by bilingual and multilingual staff,[261] the impact may be substantial.

Thus, assuming even the somewhat outdated cost estimates from the 2002 OMB report, providers are likely to incur substantial costs associated with the new Section 1557 interpretation regulations.[262] Hospital providers will not receive any funding offsets from either the HHS OCR or the Medicare program, and must instead absorb these costs directly or pass them along to other health care consumers.

IV. Provider Burden Under the 2010 ADA Regulations

The second example this Article will examine is the DOJ's 2010 regulations related to the provision of interpretation services and other auxiliary aids to deaf and hard of hearing individuals. Under the ADA, hospitals that participate in federal healthcare programs must provide communication services to those who are deaf and hard of hearing.[263] Hospitals have been subject to this general requirement since the ADA was passed in 1990 and the implementing regulations became effective in 1992.[264] On September 15, 2010, the DOJ published revised final regulations

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261. OMB E.O. 13166 COST REPORT, *supra* note 171, at 48–49, 51.

262. In addition to the costs associated with implementing the Section 1557 provisions, it is important to acknowledge that these new regulations are in addition to existing and remaining requirements imposed by other federal and state regulatory bodies. In the final rule, the OCR acknowledged:

> We decline to adopt an approach that otherwise automatically harmonizes nondiscrimination rules or deems compliance with other laws sufficient for compliance with Section 1557. As we noted above in the discussion of deeming in the General Comments, it is common for entities to be subject to multiple State and Federal regulations, even when some of those regulations have been adopted by a single Federal agency.

Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31420 (proposed May 18, 2016) (codified at 45 C.F.R. § 92).

263. *See* 42 U.S.C. § § 12181, 12182 (2018) (prohibiting discrimination based on failure to provide steps necessary to ensure that no individual with a hearing disability is excluded or denied services).

264. Nondiscrimination on the Basis of Disability by Public Accommodations and in Commercial Facilities, 56 Fed. Reg. 35544, 34468–69 (July 26, 1991) (codified at 28 C.F.R. pt. 35) [hereinafter 1991 DOJ Fed. Reg. Notice].

with more exacting requirements.[265] The 2010 regulations were part of a multiyear effort to rework the full scope of Title III ADA requirements and expanded well beyond the provision of auxiliary aids to the deaf and hard of hearing.[266]

The 2010 ADA regulations, which went into effect on March 14, 2011, substantially altered hospitals' obligations related to auxiliary aids for deaf and hard of hearing individuals.[267] Like the 2016 Section 1557 regulations pertaining to translation and interpretation services for LEP individuals, the new ADA regulations are likely to result in higher burden for providers in the provision of interpretation services. Also, like the 2016 Section 1557 regulations, the federal government did not provide a cost assessment for these new regulations. Nor did the DOJ allocate any additional funding to offset the costs of these new regulatory requirements. Providers also will not receive any additional payment for these services under the Medicare program.

A. Background and History of Interpretation Requirements for the Deaf and Hard of Hearing

The ADA was enacted on July 26, 1990, to provide comprehensive civil rights protections to individuals with disabilities in the areas of employment, public accommodations, State and local government services, and telecommunications.[268] On July 26, 1991, the DOJ issued final regulations implementing the ADA requirements, which went into effect on January 26, 1992.[269]

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265. 2010 DOJ Fed. Reg. Notice, *supra* note 22, at 56236.

266. *See* 1991 DOJ Fed. Reg. Notice, *supra* note 264, at 34466 ("The purpose of this part is to implement title III of the Americans with Disabilities Act of 1990 . . . which prohibits discrimination . . . and requires places of public accommodation and commercial facilities to be designed, constructed, and altered in compliance with the accessibility standards.").

267. *See id.* 34466 (describing the alterations to the rules on auxiliary aids).

268. *See id.* (discussing the general purpose of the ADA and its applicability in various places and occasions).

269. *Id.* at 34466.

Title III of the ADA applies to all private health care providers, regardless of the size of the entity or the number of employees.[270] Accordingly, under Title III, hospitals were required to "take those steps that may be necessary to ensure that no individual with a disability is excluded, denied services, segregated or otherwise treated differently than other individuals because of the absence of auxiliary aids and services."[271] More specifically, hospitals were required to provide "appropriate auxiliary aids and services where necessary to ensure effective communication with individuals with disabilities."[272] The 1991 regulations did not define "effective communication" or further explain how it is to be achieved.

The 1991 regulations also provided limited information regarding which auxiliary aids providers could use to achieve effective communication.[273] In the context of deaf and hard of hearing individuals, the regulation merely provided a list of appropriate "auxiliary aids and services"[274] without further elaboration. That list included:

> Qualified interpreters, note takers, computer-aided transcription services, written materials, telephone handset amplifiers, assistive listening devices, assistive listening systems, telephones compatible with hearing aids, closed caption decoders, open and closed captioning, telecommunications devices for deaf persons (TDD's), videotext displays, or other effective methods of making aurally delivered materials available to individuals with hearing impairments.[275]

The regulations defined qualified interpreter to mean "an interpreter who is able to interpret effectively, accurately and

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270. *See* 28 C.F.R. § 36.104 (2018) (detailing the applicability of the ADA). Title III applies well beyond hospitals and other health care providers, but this Article is limited in scope to addressing the specific burden for hospitals.

271. *Id.* § 36.303(a).

272. *Id.* § 36.303(c).

273. *See* 1991 DOJ Fed. Reg. Notice, *supra* note 264, at 34507–08 (stating simply that "[a] public entity shall furnish appropriate auxiliary aids and services where necessary to ensure effective communication with individuals with disabilities").

274. *Id.*

275. *Id.* at 34503.

impartially both receptively and expressively, using any necessary specialized vocabulary."[276]

Beyond these relatively limited regulatory requirements, providers were free to select the auxiliary aid judged best to provide effective communication with a deaf and hard of hearing patient in the circumstances.[277] Hospitals routinely relied upon family members and friends of deaf and hard of hearing patients to provide interpretation services or resorted to note writing to convey questions and information.[278]

B. Significant Changes to the Interpretation and Auxiliary Aid Requirements Under the 2010 DOJ Regulations

The DOJ published revised final regulations implementing Title III of the ADA on September 15, 2010.[279] These regulations were intended to "clarify and refine issues that have arisen over the past twenty years and contain new, and updated requirements."[280] Under the final regulations, which went into effect on March 15, 2011, hospitals' primary obligation did not change.[281] Hospitals were still required to "take those steps that may be necessary to ensure that no individual with a disability is excluded, denied services, segregated or otherwise treated

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276. *Id.*

277. *See id.* at 35566 ("The auxiliary aid requirement is a flexible one. A public accommodation can choose among various alternatives as long as the result is effective communication.").

278. *See ADA Requirements: Effective Communication*, U.S. DEP'T JUST., C.R. DIV. (Jan. 31, 2014) [hereinafter Effective Communication], https://www.ada.gov/effective-comm.htm (discussing the various options available to entities when communicating with individuals with communication disabilities) (on file with the Washington & Lee Journal of Civil Rights & Social Justice).

279. 2010 DOJ Fed. Reg. Notice, *supra* note 22, at 56236.

280. U.S. DEP'T JUST., C. R. DIV., ADA REQUIREMENTS: TESTING ACCOMMODATIONS 1, https://www.ada.gov/regs2014/testing_accommodations.pdf (last visited Apr. 16, 2018) (on file with the Washington & Lee Journal of Civil Rights & Social Justice).

281. *See* 2010 DOJ Fed. Reg. Notice, *supra* note 22, at 56236–37 (explaining that the final rule will "update or amend certain provisions of the title III regulation so that they comport with the Department's legal and practical experiences in enforcing the ADA . . .").

differently than other individuals because of the absence of auxiliary aids and services."[282]

However, under the new regulations, hospitals were required to comply with more stringent requirements to meet those obligations.[283] Specifically, the new regulations expanded the scope of individuals entitled to auxiliary aids; provided additional direction regarding effective communication; included new limitations on ad-hoc interpreters, such as family and friends; included specific requirements for video interpretation services; and clarified that auxiliary aids must be provided in a timely manner.[284] These regulations were supplemented by guidance documents from the DOJ Civil Rights Division, Disability Rights Section, which provided additional detail regarding implementation of the new regulations in the healthcare setting.[285]

1. Expanded Scope of Services

Prior to the 2010 regulations, hospitals generally understood that they had an obligation to provide auxiliary aids to disabled patients and other hospital patrons, such as attendees at community events or health and wellness classes.[286] However, the 2010 regulations explicitly expanded the scope of individuals entitled to auxiliary aids and services. Under the 2010 regulations, hospitals now have "an obligation to provide effective communication" to patients and patrons and to "companions who are individuals with disabilities."[287] The DOJ defined "companion" to mean "a family member, friend, or associate of an individual seeking access to, or participating in, the goods, services, facilities, privileges, advantages, or accommodations of a public

282. 28 C.F.R. § 36.303(a) (2018).

283. *Id.* at § 36.303.

284. *Id.*

285. *See ADA Business BRIEF: Communicating With People Who Are Deaf or Hard of Hearing in Hospital Settings*, U.S. DEP'T JUST., C.R. DIV. (Oct. 2003) [hereinafter ADA Business Brief], https://www.ada.gov/hospcombr.htm (clarifying requirements under the Americans With Disabilities Act) (on file with the Washington & Lee Journal of Civil Rights & Social Justice).

286. *See supra* Part IV. Provider Burden Under the 2010 ADA Regulations

287. 28 C.F.R § 36.303(c)(1) (2018).

accommodation, who, along with such individual, is an appropriate person with whom the public accommodation should communicate."[288] Thus, under the new regulations, the DOJ clarified that even in cases where a patient or patron is not an individual with a disability, if his or her companion has a disability, that companion is entitled to services.[289]

When the proposed regulations were published, a number of medical providers objected to the inclusion of companions in the definition of individuals entitled to services.[290] Specifically, in the final rule the DOJ explained:

> Some in the medical community objected to the inclusion of any regulatory language regarding companions, asserting that such language is overbroad, seeks services for individuals whose presence is neither required by the public accommodation nor necessary for the delivery of the services or goods, places additional burdens on the medical community, and represents an uncompensated mandate. One medical association commenter stated that such a mandate was particularly burdensome in situations where a patient is fully and legally capable of participating in the decision-making process and needs little or no assistance in obtaining care and following through on physician's instructions.[291]

Another commenter suggested "that companions should receive auxiliary aids and services only when necessary to ensure effective communication with the person receiving the public accommodation's services."[292]

Despite these suggestions from some in the medical community, the DOJ declined to limit the scope of companions entitled to services in the final rule, stating that the regulation reflected the DOJ's "longstanding position that public accommodations are required to provide effective communication to companions when they accompany patients to medical care

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288. *Id.* at § 36.303(c)(1)(i).

289. *See* 2010 DOJ Fed. Reg. Notice, *supra* note 22, at 56281 ("There are many instances in which such an individual may not be an individual with a disability but his or her companion is an individual with a disability. The effective communication requirement applies equally to that companion.").

290. *See generally id.* describing objections to the 2010 DOJ regulation).

291. *Id.*

292. *Id.*

providers for treatment."[293] As demonstrated by the comments from some health care providers, this "longstanding position" was not known to many in the medical community.[294]

2. Expanded Effective Communication Requirements

Under the 2010 regulations, providers retained the obligation to "furnish appropriate auxiliary aids and services where necessary to ensure effective communication with individuals with disabilities."[295] In the 2010 regulations, and in several guidance documents that followed, the DOJ provided more information and more stringent requirements regarding what constituted "effective communication" than had been included in the 1991 regulations.[296] The DOJ explained in the 2010 final rule that despite the fact that providers have had an obligation to provide sufficient auxiliary aids for effective communication since the ADA was enacted, the DOJ had investigated a number hospitals for failing to ensure effective communication with disabled individuals.[297] The new regulations and guidance documents were intended to prevent some of the investigated issues.[298]

In the 2010 regulations, the DOJ once again declined to specifically define "effective communication."[299] The regulations did, for the first time, offer more specific direction to providers on selecting an auxiliary aid that ensures effective communication

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293. *Id.* at 56283.

294. *Id.* at 56281.

295. *Id.* at 56280.

296. *See id.* (describing the requirements of the new regulation).

297. *See id.* ("The Department has investigated hundreds of complaints alleging that public accommodations have failed to provide effective communication, and many of these investigations have resulted in settlement agreements and consent decrees.").

298. *See id.* ("During the course of these investigations, the Department has determined that public accommodations sometimes misunderstand the scope of their obligations under the statute and the regulation. Section 36.303 in the final rule codifies the Department's longstanding policies in this area . . . .").

299. *See id.* at 56253 (referencing "effective communication" but providing no definition of it).

with deaf or hard of hearing individuals.[300] Specifically, the regulations state:

> The type of auxiliary aid or service necessary to ensure effective communication will vary in accordance with the method of communication used by the individual; the nature, length, and complexity of the communication involved; and the context in which the communication is taking place. A public accommodation should consult with individuals with disabilities whenever possible to determine what type of auxiliary aid is needed to ensure effective communication, but the ultimate decision as to what measures to take rests with the public accommodation, provided that the method chosen results in effective communication. In order to be effective, auxiliary aids and services must be provided in accessible formats, in a timely manner, and in such a way as to protect the privacy and independence of the individual with a disability.[301]

The 2010 regulations also included a more detailed list of suggested auxiliary aids for providers to consider when selecting an aid to ensure effective communication, which was more expansive than the 1991 suggestions:

> Qualified interpreters on-site or through video remote interpreting (VRI) services; notetakers; real-time computer-aided transcription services; written materials; exchange of written notes; telephone handset amplifiers; assistive listening devices; assistive listening systems; telephones compatible with hearing aids; closed caption decoders; open and closed captioning, including real-time captioning; voice, text, and video-based telecommunications products and systems, including text telephones (TTYs), videophones, and captioned telephones, or equally effective telecommunications devices; videotext displays; accessible electronic and information technology; or other effective methods of making aurally delivered information available to individuals who are deaf or hard of hearing.[302]

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300. *See* 28 C.F.R § 36.303(c)(1)(ii) (2018) (explaining that health care providers have a duty to provide appropriate auxiliary aids and services when necessary to ensure that communication with people who are deaf or hard of hearing is as effective as communication with others).

301. *Id.*

302. *Id.* at § 36.303(b)(1).

The DOJ guidance documents provided additional information for providers seeking to navigate the new regulations. Specifically, in guidance the DOJ Civil Rights Division reiterated, "[t]he key to deciding what aid or service is needed to communicate effectively is to consider the nature, length, complexity and context of the communication as well as the person's normal method(s) of communication."[303] The DOJ also provided more detailed examples of aids the agency felt were sufficient in specific types of interactions, including:

> Exchanging written notes or pointing to items for purchase will likely be effective communication for brief and relatively simple face-to-face conversations, such as a visitor's inquiry about a patient's room number or a purchase in the gift shop or cafeteria.
>
> Written forms or information sheets may provide effective communication in situations where there is little call for interactive communication, such as providing billing and insurance information or filling out admission forms and medical history inquiries.
>
> For more complicated and interactive communications, such as a patient's discussion of symptoms with medical personnel, a physician's presentation of diagnosis and treatment options to patients or family members, or a group therapy session, it may be necessary to provide a qualified sign language interpreter or other interpreter.[304]

The novel guidance went on to specifically enumerate the following "situations where an interpreter may be required for effective communication":

- Discussing a patient's symptoms and medical condition, medications, and medical history;
- explaining and describing medical conditions, tests, treatment options, medications, surgery and other procedures;
- providing a diagnosis, prognosis, and recommendation for treatment

303. Effective Communication, *supra* note 278.

304. ADA Business Brief, *supra* note 285.

- obtaining informed consent for treatment;
- communicating with a patient during treatment, testing procedures, and during physician's rounds;
- providing instructions for medications, post-treatment activities, and follow-up treatments;
- providing mental health services, including group or individual therapy, or counseling for patients and family members;
- providing information about blood or organ donations;
- explaining living wills and powers of attorney;
- discussing complex billing or insurance matters; and
- making educational presentations, such as birthing and new parent classes, nutrition and weight management counseling, and CPR and first aid training.[305]

The DOJ guidance also clarified the importance of determining the disabled individual's usual method of communication, explaining that not all deaf and hard of hearing individuals are fluent in American Sign Language (ASL).[306] Many deaf and hard or hearing individuals use ASL, a visually interactive language that uses a combination of hand motions, body gestures, and facial expressions, but does not directly translate into English.[307] Others used signed English, a form of sign language that does directly translate into English.[308] However, "[n]ot all people who are deaf or hard of hearing are trained in sign language. Some individuals with hearing disabilities are trained in speech reading (lip reading) and can understand spoken words fairly well with assistance from an oral interpreter."[309] Those individuals may rely on "[o]ral interpreters who are specially trained to articulate speech silently and clearly,

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305. *Id.*

306. *See id.* (explaining the importance of determining which method of communication deaf and hard of hearing individuals use to communicate).

307. *See id.* (describing sign language as a visually interactive language).

308. *See id.* (noting the difference between American Sign Language and Signed English).

309. *Id.*

sometimes rephrasing words or phrases to give higher visibility on the lips. Natural body language and gestures are also used."[310]

Some individuals instead rely on cued speech interpreters, who function "in the same manner as an oral interpreter except that he or she also uses a hand code, or cue, to represent each speech sound."[311] However, "[m]any people who are deaf or hard of hearing are not trained in either sign language or speech reading."[312] Those individuals may rely on "CART . . . a service in which an operator types what is said into a computer that displays the typed words on a screen."[313] The DOJ cautioned that providers must thus take into account the type of interpretation services needed to meet the deaf or hard of hearing individual's unique communication needs.[314]

While providers have long sought additional guidance from the DOJ regarding how to ensure effective communication with the deaf and hard of hearing, the 2010 regulations are likely to increase costs for hospital providers. The 2010 regulations directed providers to engage in a complex analysis to decide on the appropriate auxiliary aid for each encounter with a deaf or hard of hearing individual.[315] That calculus must now include the nature of the interaction; the need for interpretation or other auxiliary aids; the deaf or hard of hearing individual's primary mode of communication; and which auxiliary aid is best suited to ensure effective communication under the circumstances.[316]

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310. *Id.*

311. *Id.*

312. *Id.*

313. *Id.*

314. *See id.* ("Hospitals should develop protocols and provide training to ensure that staff know how to obtain interpreter services and other communication aids and services when needed by persons who are deaf or hard of hearing.").

315. *Id.*

316. *See* 2010 DOJ Fed. Reg. Notice, *supra* note 22, at 56253–54 (instructing hospital instructors to provide more individualized interpretation and other auxiliary aids).

3. Increased Interpreter Qualification Requirements

The 2010 regulations also imposed substantial new limits on which individuals hospitals could use to provide interpretation services for the deaf and hard of hearing.[317] Both the 1991 and 2010 regulations used the same definition of "qualified interpreter."[318] That is, "an interpreter who is able to interpret effectively, accurately and impartially both receptively and expressively, using any necessary specialized vocabulary."[319] However, in the 2010 regulations, the DOJ substantially limited the use of ad-hoc interpreters to provide communication with deaf and hard of hearing individuals.[320]

Prior to the 2010 regulations, hospitals regularly relied upon deaf and hard of hearing patients' companions to provide interpretation services.[321] In the 2010 regulations, the DOJ expressly stated that providers are not permitted to require a deaf or hard of hearing individual to bring another individual to interpret for him or her.[322] Further, even if a deaf or hard of hearing individual voluntarily brings an adult individual to interpret for him or her, providers are precluded from using that accompanying adult as an interpreter except in two limited circumstances.[323]

First, accompanying adults may be used as interpreters in "an emergency involving an imminent threat to the safety or welfare of an individual or the public where there is no interpreter available."[324] Second, accompanying adults may be used as interpreters when "the individual with a disability specifically

317. *See* ADA Business Brief, *supra* note 285 (detailing communication requirements for individuals in hospital settings who are deaf or hard of hearing).

318. *See* 28 C.F.R. § 36.104 (2018) (defining who is a qualified interpreter under the regulation).

319. *Id.*

320. *See* 2010 DOJ Fed. Reg. Notice, *supra* note 22, at 56253–54 (describing the circumstances in which the use of ad-hoc interpreters may be employed).

321. *See* Effective Communication, *supra* note 278 ("Historically, many covered entities have expected a person who uses sign language to bring a family member or friend to interpret for him or her.").

322. 28 C.F.R § 36.303(c)(2).

323. *See id.* § 36.303(c)(3)(i)–(ii) (listing two exceptions to the general rule).

324. *Id.* § 36.303(c)(3)(i).

requests that the accompanying adult interpret or facilitate communication, the accompanying adult agrees to provide such assistance," and the provider has determined "reliance on that adult for such assistance is appropriate under the circumstances."[325] In guidance, the DOJ cautioned that under this second exception, the provider may not use the accompanying adult if there is reason to doubt the accompanying adult's impartiality or effectiveness, which could occur if the accompanying adult feels conflicted about communicating the requested information to the disabled individual or has a personal stake in the outcome of the communication.[326]

Providers are further restricted from using minors to provide interpretation services for the deaf or hard of hearing.[327] In the case of accompanying minors, providers "shall not rely on a minor child to interpret or facilitate communication, except in an emergency involving an imminent threat to the safety or welfare of an individual or the public where there is no interpreter available" even if the disabled individual specifically requests the minor provide interpretations services.[328]

4. Novel Video Remote Interpreting Requirements

Like the new requirements for VRI services in the Section 1557 implementing regulations,[329] providers must comply with new VRI regulations when providing video interpretation services to the deaf and hard of hearing. Providers that choose to use VRI services for interpretation must ensure that the VRI provides:

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325. *Id.* § 36.303(c)(3)(ii).

326. Effective Communication, *supra* note 278.

327. *See* 28 C.F.R § 36.303(c)(4) (2018) ("A public accommodation shall not rely on a minor child to interpret or facilitate communication, except in an emergency involving an imminent threat to the safety or welfare of an individual or the public where there is no interpreter available.").

328. *Id.*

329. *See* Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 3140–70 (proposed May 18, 2016) (codified at 45 C.F.R. § 92) (explaining requirements when providing "a qualified interpreter for an individual with limited English proficiency through video remote interpreting services").

> (1) Real-time, full-motion video and audio over a dedicated high-speed, wide-bandwidth video connection or wireless connection that delivers high-quality video images that do not produce lags, choppy, blurry, or grainy images, or irregular pauses in communication;
>
> (2) A sharply delineated image that is large enough to display the interpreter's face, arms, hands, and fingers, and the participating individual's face, arms, hands, and fingers, regardless of his or her body position;
>
> (3) A clear, audible transmission of voices; and
>
> (4) Adequate training to users of the technology and other involved individuals so that they may quickly and efficiently set up and operate the VRI.[330]

These new controls on the use of VRI are intended to ensure high quality translation for deaf and hard of hearing, but are also likely to increase costs as providers seek technology that complies with the VRI requirements.

5. Novel Timeliness Requirements

In the 2010 regulations regarding effective communication, the DOJ clarified that "[i]n order to be effective, auxiliary aids and services must be provided in accessible formats, *in a timely manner*, and in such a way as to protect the privacy and independence of the individual with a disability."[331] In guidance, the DOJ explained that hospitals must have arrangements in place to ensure interpreters are "readily available on a scheduled basis and on an unscheduled basis with minimal delay."[332] Additionally, providers must have on-call arrangements for interpreters after hours and in emergency situations.[333] Finally, "[h]ospitals should develop protocols and provide trainings to ensure that staff know

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330. 28 C.F.R § 36.303(f).

331. *Id.* at § 36.303(c)(1)(ii) (emphasis added).

332. ADA Business Brief, *supra* note 285.

333. *See id.* ("Hospitals should have arrangements in place to ensure that qualified interpreters are readily available on a scheduled basis and on an unscheduled basis with minimal delay, including on-call arrangements for after-hours emergencies.").

how to obtain interpreter services and other communication aides and services when needed . . . ."[334]

C. Increased Costs to Hospitals Under the 2010 ADA Regulations

It is difficult to estimate the overall cost of providing interpretation and other auxiliary aids to Medicare patients, as the DOJ did not include any cost estimates or other specific burden analysis for this requirement in the 2010 final rule or in the original final rule published in 1991. However, it would be helpful to examine how many Medicare beneficiaries are deaf or hard of hearing to get a sense of the potential scope of hospitals' obligations.

In April 2017, CMS conducted a study of communication needs amongst Medicare beneficiaries.[335] In the study, which relied upon 2014 Medicare data, CMS noted that there are fifty-two million Medicare beneficiaries in the United States.[336] Further, approximately 14.7 percent of those Medicare beneficiaries are deaf or hard of hearing.[337] Thus, CMS estimates over 7.7 million Medicare beneficiaries are deaf or hard of hearing.[338] Under the ADA, hospitals must provide appropriate auxiliary aids, including interpretation services when warranted, to all of these beneficiaries if needed to engage in effective communication.[339] Additionally, under the new 2010 rule, hospitals must also provide services to all Medicare beneficiaries' deaf or hard of hearing companions, further expanding the potential scope.[340]

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334. *Id.*

335. CTR. FOR MEDICARE & MEDICAID SERVS., UNDERSTANDING COMMUNICATION AND LANGUAGE NEEDS OF MEDICARE BENEFICIARIES 4 (Apr. 2017), https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Issue-Briefs-Understanding-Communication-and-Language-Needs-of-Medicare-Beneficiaries.pdf (on file with the Washington & Lee Journal of Civil Rights & Social Justice).

336. *Id.* at 8.

337. *Id.* at 10.

338. *Id.*

339. *Id.* at 3.

340. *Id.*

Hospitals are required to provide auxiliary aids to deaf and hard of hearing patients and companions free of charge.[341] The federal government did not allocate any funds to hospitals to pay for the interpretation services and other auxiliary aids required under the more onerous 2010 implementing regulations.[342] Further, Medicare, the largest government payer of hospital services, does not reimburse hospitals for expenses associated with providing interpreters or other auxiliary aids to Medicare patients or patient-companions for the purposes of ensuring effective communication during a Medicare covered hospital service.[343] Hospitals are also prohibited from seeking reimbursement for interpreters or other aids directly from patients or their companions.[344] Hospitals must instead fully incur the cost of providing these services to Medicare patients.[345]

National organizations, such as the National Association of the Deaf, acknowledge that required interpretation services may exceed the reimbursement hospitals receive from Medicare for a deaf or hard of hearing patient's treatment. Specifically, the association explains:

> In some situations, the cost of providing an auxiliary aid or service (e.g., a qualified interpreter) may exceed the charge [for] the health care service. A health care provider is expected to treat the costs of providing auxiliary aids and services as part of the overhead costs of operating a business. Accordingly, so long as the provision of the auxiliary aid or service does not

341. *See* 28 C.F.R. § 36.301(c) (2018) ("A public accommodation may not impose a surcharge on a particular individual with a disability or any group of individuals with disabilities to cover the costs of measures . . . .").

342. *See generally* 2010 DOJ Fed. Reg. Notice, *supra* note 22.

343. *See supra* Part III(C, Medicare *Payment for Hospital Services is Not Responsive to Novel Regulatory Burden*

344. 28 C.F.R. § 36.301(c).

345. Some small business, including physician practices, are permitted to recoup the cost of interpretation services and other expenditures to aid disabled individuals through the Disabled Access Tax Credit and other business deductions. To qualify for the tax credit, the practice must have less than thirty employees or annual revenue of under $1,000,000. 26 U.S.C. § 44 (2018). This limited tax credit is not available to hospitals.

> impose an undue burden on the provider's business, the provider is obligated to pay for the auxiliary aid or service.[346]

Individual hospitals have also experienced this phenomenon. In 2017 the author spoke to one community hospital in Virginia which provided an outpatient family practice visit to a Medicare patient requiring ASL translation services.[347] Medicare reimbursed the hospital $51.00 for the visit. [348] This particular hospital, which is in a rural area of Virginia, obtained ASL interpretation services for that visit from an independent company. [349] The company required that the hospital pay for a minimum of two hours of translation services, at a cost of $80.00 per hour. [350] Thus, for just this one visit, the hospital sustained a loss of $109.00. [351]

1. The Limited Scope of the "Undue Burden" Exception

The ADA includes a limited exception for providers when an auxiliary aid or service would result in an undue burden to the health care provider.[352] When considering whether a specific aid or service constitutes an undue burden, providers must examine the nature and cost of the auxiliary aid or service; the overall financial resources of the health care provider and the impact of the auxiliary aid on those resources; the number of people employed by the provider; and the overall size, financial resources, and characteristics of the hospital's parent corporation or entity, if applicable.[353]

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346. *Questions and Answers for Health Care Providers*, NAT'L ASS'N DEAF, https://www.nad.org/resources/health-care-and-mental-health-services/health-care-providers/questions-and-answers-for-health-care-providers/ (last visited Apr. 16, 2018) (on file with the Washington & Lee Journal of Civil Rights & Social Justice).

347. Rachel Suddarth, STUDY OF MEDICARE COVERAGE OF INTERPRETATION SERVICES IN VIRGINIA (2017) (on file with author).

348. *Id.*

349. *Id.*

350. *Id.*

351. *Id.*

352. *Questions and Answers for Health Care Providers*, *supra* note 346.

353. 28 C.F.R. § 36.104 (2018).

A provider does not meet the "undue burden" test by merely showing that providing the auxiliary aid will exceed the overall reimbursement received from Medicare for treating the patient.[354] Instead, the provider must show that providing the auxiliary aid or service would constitute a significant expense given the providers total financial resources.[355] Further, even when a provider determines a specific auxiliary aid would constitute an undue burden, the provider still has the duty to furnish an alternative auxiliary aid or service that would not result in an undue burden and, to the maximum extent possible, would ensure effective communication.[356]

Hospitals will rarely avoid providing auxiliary aids on the basis of the narrow "undue burden" exception because of their substantial financial resources and ability to utilize alternative auxiliary aids to accomplish the desired communication. Hospital providers are thus likely to incur substantial costs associated with the new requirements and will not receive any funding offsets from either the federal government or the Medicare program.

IV. Conclusion

Each year, hospitals that participate in the Medicare program are subjected to increased federal regulatory requirements. Many novel regulations serve laudable goals, such is improving patient safety, access to care, and quality. Often, these regulations also impose heavy burdens on the implementing providers. Federal agencies routinely issue new or revised regulations without allocating any funding to offset the burden of implementing hospital providers. Hospitals must comply with federal regulations as a condition of participation in the Medicare program, yet

354. *See* Effective Communication, *supra* note 278 ("[In] determining whether a particular aid or service would result in an undue burden, a Title III entity should take into consideration the nature and cost of the aid or service relative to their size, overall financial resources, and overall expenses.").

355. *Id.*

356. *See* 28 C.F.R. § 36.303(f) ("When an undue burden can be shown, the health care provider still has the duty to furnish an alternative auxiliary aid or service that would not result in an undue burden and, to the maximum extent possible, would ensure effective communication.").

Medicare reimbursement does not change to capture implementation costs. Thus, hospitals are required to implement federal regulatory requirements at their own expense.

Despite the financial pressures associated with unfunded federal regulatory mandates, hospitals can rarely afford to opt out of the Medicare program. Hospitals are reliant on Medicare reimbursement to offset operating costs. Further, Medicare beneficiaries represent a substantial segment of hospitals' potential patient population. Medicare participating hospitals thus remain in the program and either absorb the regulatory compliance costs directly or pass them along to other health care consumers.

This Article examined two examples of unfunded regulatory mandates, and the impact those regulations are likely to have on hospital providers. First, this Article discussed the HHS OCR's 2016 Section 1557 implementing regulations. As detailed above the 2016 Section 1557 regulations imposed new requirements on hospital providers when offering translation and interpretation services to LEP individuals.[357] With respect to translation services, providers must now use qualified translators and include new notice and tagline provisions in all significant publications.[358] With respect to interpretation services, providers must offer services to an expanded scope of individuals, meet more stringent interpreter requirements that eliminate many free sources of translation services, and adhere to novel video interpretation requirements.[359]

While these new regulatory requirements were intended to serve the laudable goal of improving communication with LEP individuals in health care settings, they are likely to impose significant new burdens on hospital providers. The HHS OCR failed to provide a cost estimate for the new requirements, making it difficult to assess the burden imposed by the regulations and weigh that burden against the anticipated benefits. Further, while even the HHS OCR acknowledged that the 2010 regulatory requirements might impose novel burden on implementing

357. Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31375 (proposed May 18, 2016) (codified at 45 C.F.R. § 92).

358. *Id.* at 31394.

359. 45 C.F.R. § 92.201 (2018).

providers, the agency failed to allocate funds to reimburse providers for associated costs.[360] Hospitals also did not receive additional reimbursement from the Medicare program for costs associated with providing translation or interpretation services to LEP Medicare beneficiaries.

Second, this Article discussed the DOJ's 2010 ADA regulations related to interpretation services and other auxiliary aids to deaf and hard of hearing individuals. Under the 2010 regulations, the DOJ expanded the scope of the hospitals' service obligation to include both patients and companions.[361] Further, the 2010 regulations and associated guidance directed providers to conduct a complex analysis to determine what auxiliary aids will permit effective communication and to provide those aids within a reasonable timeframe.[362] The regulations also limited the use of ad-hoc family and friend interpreters and imposed strict requirements for video interpretation services.[363] These changes are likely to increase the cost of interpretation services and other auxiliary aids for deaf and hard of hearing individuals.

While the 2010 ADA regulatory changes indicate that provider burden will increase, again the federal government did not provide any assessment of the implementation costs. The DOJ also did not allocate any funds to reimburse providers for these novel costs and the Medicare program will not reimburse hospitals for additional costs associated with providing these services to deaf and hard of hearing Medicare beneficiaries and their companions.[364]

These two regulations are but small examples of a larger pattern of unfunded mandates stressing the finances of Medicare participating hospital providers. A study by the American Hospital Association indicated that the majority of hospital providers are underpaid by the Medicare program,[365] meaning Medicare reimburses providers at less than the cost of providing services to Medicare beneficiaries. As the federal government continues to

360. *See generally* OMB E.O. 13166 COST REPORT, *supra* note 171.

361. 28 C.F.R § 36.303(c)(1).

362. *Id.*

363. Effective Communication, *supra* note 278.

364. *See generally* 2010 DOJ Fed. Reg. Notice, *supra* note 22.

365. AHA UNDERPAYMENT FACT SHEET, *supra* note 38, at 2.

issue unfunded regulatory mandates, this underpayment by the Medicare program is likely to get worse.

It is difficult to study the exact impact of unfunded mandates as many agencies fail to produce cost estimates for new regulations. However, close examination of new and revised regulations indicates large potential new costs. As the United States continues to grapple with rising health care costs, increased and improved study of the impact of regulatory burden on health care providers is warranted. Federal agencies should perform more comprehensive assessments of the costs associated with novel or revised regulations at the proposed and final rule stages. These cost estimates will permit both accurate tracking of regulatory burden and better assessment of whether the increased costs of new regulatory requirements are warranted given the benefits afforded by those regulations.

SYMPOSIUM KEYNOTE