

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

---

THE AMERICAN HOSPITAL ASSOCIATION, )  
*et al.*, )

Plaintiffs, )

v. )

Case No. 1:14-cv-00609

SYLVIA MATHEWS BURWELL, in her )  
official capacity as Secretary of Health and )  
Human Services, )

Defendant. )

---

**PLAINTIFFS’ MOTION FOR SUMMARY JUDGMENT**

Plaintiffs the American Hospital Association, Banner Health, Mount Sinai Hospital, Einstein Healthcare Network, Wake Forest Baptist Medical Center, Greater New York Hospital Association, Healthcare Association of New York State, New Jersey Hospital Association, and The Hospital & Healthsystem Association of Pennsylvania respectfully submit this motion for summary judgment.

On August 19, 2013, the Secretary of Health and Human Services (“Secretary”) adopted three unlawful policies: (1) a new test for determining when a person is an “inpatient” for purposes of Medicare reimbursement, (2) a one-year time limit that applies to certain requests for Medicare Part B payment, and (3) a new requirement for written physician orders as a condition of Medicare payment for every inpatient stay. These policies impose arbitrary standards on hospitals and unlawfully deprive them of the Medicare reimbursement to which they are entitled and on which they rely to provide patient care. As set forth in the accompanying memorandum, the Secretary promulgated these policies without any reasoned basis for doing so and in violation

of the Medicare Act, Title VIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq.*, and the Administrative Procedure Act, 5 U.S.C. §§ 551 *et seq.*

Plaintiffs' claims are grounded in facts conclusively established by the administrative record, or lack thereof; no genuine issues of material fact prevent the Court from granting Plaintiffs summary judgment as a matter of law. *See* Fed. R. Civ. P. 56(c).

Dated: August 4, 2014

Respectfully Submitted,

/s/ Dominic F. Perella  
Sheree R. Kanner (D.C. Bar No. 366926)  
Dominic F. Perella\* (D.C. Bar No. 976381)  
Margia K. Corner (D.C. Bar No. 1005246)  
Jennifer D. Brechbill (D.C. Bar No. 1011454)  
HOGAN LOVELLS US LLP  
555 Thirteenth Street, N.W.  
Washington, D.C. 20004  
(202) 637-5600

\* *Counsel of Record*

Melinda Reid Hatton (D.C. Bar No. 419421)  
Lawrence Hughes (D.C. Bar. No. 460627)  
AMERICAN HOSPITAL ASSOCIATION  
325 Seventh Street, NW  
Washington, DC 20001  
(202) 638-1100

*Attorneys for Plaintiffs*

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, )  
et al., )

Plaintiffs, )

v. )

Case No. 1:14-cv-00609

SYLVIA MATHEWS BURWELL, in her )  
official capacity as Secretary of Health and )  
Human Services, )

Defendant. )

**PLAINTIFFS’ MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF  
PLAINTIFFS’ MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO  
DEFENDANT’S MOTION TO DISMISS**

/s/ Dominic F. Perella

Sheree R. Kanner (D.C. Bar No. 366926)  
Dominic F. Perella\* (D.C. Bar No. 976381)  
Margia K. Corner (D.C. Bar No. 1005246)  
Jennifer D. Brechbill (D.C. Bar No. 1011454)  
HOGAN LOVELLS US LLP  
555 Thirteenth Street, N.W.  
Washington, D.C. 20004  
(202) 637-5600

*\* Counsel of Record*

Melinda Reid Hatton (D.C. Bar No. 419421)  
Lawrence Hughes (D.C. Bar. No. 460627)  
AMERICAN HOSPITAL ASSOCIATION  
325 Seventh Street, NW  
Washington, DC 20001  
(202) 638-1100

*Attorneys for Plaintiffs*

Dated: August 4, 2014

**TABLE OF CONTENTS**

	<u>Page</u>
INTRODUCTION .....	1
FACTUAL BACKGROUND .....	5
STANDARD OF REVIEW .....	9
ARGUMENT .....	10
I. PLAINTIFFS ARE ENTITLED TO SUMMARY JUDGMENT. ....	10
A. The Two-Midnights Rule Is Arbitrary and Capricious.....	10
B. The Application of the One-Year Filing Rule to Rebilled Part B Claims Is Arbitrary and Capricious.....	17
C. The Physician-Order Rule Violates the Medicare Act and the APA.....	24
II. THE GOVERNMENT’S MOTION TO DISMISS SHOULD BE DENIED.....	28
A. This Court Has Jurisdiction Over Plaintiffs’ Two-Midnights Challenge. ....	28
1. Plaintiffs Have Satisfied the Presentment Requirement. ....	28
2. Exhaustion of Administrative Remedies Would Be Futile.....	30
B. This Court Has Jurisdiction Over Plaintiffs’ Physician-Order Challenge. ....	35
1. Plaintiffs Have Presented Their Claims And Exhaustion Should Be Waived. ....	35
2. Plaintiffs Have Standing. ....	36
3. Plaintiffs’ Physician-Order Challenge Is Ripe.....	38
C. This Court Has Jurisdiction Over The One-Year Time Limit Challenge. ....	39
1. Plaintiffs Have Presented Their Claims And Exhaustion Should Be Waived. ....	39
2. Plaintiffs Have Standing. ....	40
3. The Secretary’s Characterization Of Plaintiffs’ One-Year Time Limit Challenge Should Be Rejected.....	41
CONCLUSION.....	45

**TABLE OF AUTHORITIES**

CASES	PAGE(S)
<i>Abbott Labs. v. Portland Retail Druggists Ass’n, Inc.</i> , 425 U.S. 1 (1976).....	11
<i>Abbott-Northwestern Hosp. v. C.I.R.</i> , 1996 WL 438847 (Minn. Tax 1996).....	12
* <i>Action Alliance of Senior Citizens v. Johnson</i> , 607 F. Supp. 2d 33 (D.D.C. 2009) .....	29, 30, 35, 39
<i>Action Alliance of Senior Citizens v. Sebelius</i> , 607 F.3d 860 (D.C. Cir. 2010).....	29, 30, 35, 39
<i>Am. Petroleum Inst. v. E.P.A.</i> , 683 F.3d 382 (D.C. Cir. 2012).....	39
<i>Am. Petroleum Inst. v. Johnson</i> , 541 F. Supp. 2d 165 (D.D.C. 2008).....	14, 15, 26
<i>Babbitt v. United Farm Workers Nat’l Union</i> , 442 U.S. 289 (1979).....	40
<i>Bonkowski v. Oberg Indus., Inc.</i> , --- F.Supp.2d ----, 2014 WL 199790 (W.D. Pa. 2014) .....	12
<i>Bowen v. City of New York</i> , 476 U.S. 467 (1986).....	30
<i>Bowen v. Mich. Acad. of Family Physicians</i> , 476 U.S. 667 (1986).....	44
<i>Califano v. Goldfarb</i> , 430 U.S. 199 (1977).....	34, 40
<i>Cape Cod Hosp. v. Sebelius</i> , 630 F.3d 203 (D.C. Cir. 2011).....	28
<i>Catholic Health Initiatives Iowa Corp. v. Sebelius</i> , 718 F.3d 914 (D.C. Cir. 2013).....	12
* <i>Chevron U.S.A. Inc. v. Natural Res. Def. Council</i> , 467 U.S. 837 (1984).....	passim

*City of Brookings Mun. Tel. Co. v. F.C.C.*,  
822 F.2d 1153 (D.C. Cir. 1987).....22

\**Council for Urological Interests v. Sebelius*,  
668 F.3d 704 (D.C. Cir. 2011).....4, 44, 45

*Dabertin v. HCR Manor Care, Inc.*,  
373 F.3d 822 (7th Cir. 2004) .....14

*Deppenbrook v. Pension Ben. Guar. Corp.*,  
950 F. Supp. 2d 68 (D.D.C. 2013) (Walton, J.).....5

*DL v. District of Columbia*,  
450 F. Supp. 2d 11, 18 (D.D.C. 2006) .....32, 36, 39

*Electric Power Supply Ass’n v. F.E.R.C.*,  
--- F.3d ---, 2014 WL 2142113 (D.C. Cir. May 23, 2014) .....17

*Etelson v. Office of Pers. Mgmt.*,  
684 F.2d 918 (D.C. Cir. 1982).....34, 40

*Evans v. First Mount Vernon, ILA*,  
786 F. Supp. 2d 347 (D.D.C. 2011) .....10

*Fund for Animals, Inc. v. Norton*,  
322 F.3d 728 (D.C. Cir. 2003).....40

*General Motors Corp. v. Ruckelshaus*,  
742 F.2d 1561 (D.C. Cir. 1984).....26

*Georgetown University Hospital v. Bowen*,  
821 F.2d 750 (D.C. Cir. 1987) *aff’d*, 488 U.S. 204 (1988).....26

*Grunewalv v. Jarvis*,  
930 F. Supp. 2d. 73 (D.D.C. 2013).....5

\**Hall v. Sebelius*,  
689 F. Supp. 2d 10 (D.D.C. 2009) .....30, 32, 36, 39

*Harbert v. Healthcare Servs. Group, Inc.*,  
391 F.3d 1140 (10th Cir. 2004) .....14

*Hearth, Patio & Barbecue Ass’n v. U.S. Dep’t of Energy*,  
706 F.3d 499 (D.C. Cir. 2013) .....16, 17

*Heckler v. Lopez*,  
464 U.S. 879 (1983).....29

*Hosp. of Univ. of Pa. v. Sebelius*,  
847 F. Supp. 2d 125 (D.D.C. 2012) .....9

*Hotze v. Sebelius*,  
2014 WL 109407 (S.D. Tex. Jan. 10, 2014).....41

*Int’l Ladies’ Garment Workers’ Union v. Donovan*,  
722 F.2d 795 (D.C. Cir. 1983) .....26

*Kaiser Found. Hosps. v. Sebelius*,  
828 F. Supp. 2d 193 (D.D.C. 2011), *aff’d*, 708 F.3d 226 (D.C. Cir. 2013).....9

*Koch Foods, Inc. v. Sec’y, U.S. Dep’t of Labor*,  
712 F.3d 476 (11th Cir. 2013) .....16

*Lake Pilots Ass’n, Inc. v. U.S. Coast Guard*,  
257 F. Supp. 2d. 148 (D.D.C. 2003) .....39

*Lilliputian Sys., Inc. v. Pipeline & Hazardous Materials Safety Admin.*,  
741 F.3d 1309 (D.C. Cir. 2014).....28

*Linguist v. Bowen*,  
813 F.2d 844 (8th Cir. 1987) .....29

*Lujan v. Defenders of Wildlife*,  
504 U.S. 555 (1992).....36, 40, 41

*Mathews v. Eldridge*,  
424 U.S. 319 (1976).....3, 29

*McNary v. Haitian Refugee Ctr., Inc.*,  
498 U.S. 479 (1991).....44

*Mead v. Holder*,  
766 F. Supp. 2d 16 (D.D.C. 2011).....41

*Methodist Hosps., Inc. v. Lake Cnty. Property Tax Assessment Bd. of Appeals*,  
862 N.E.2d 335 (2007).....12

*Moreland v. United States*,  
968 F.2d 655 (8th Cir. 1992) .....16

*Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*,  
463 U.S. 29 (1983).....22

*Northpoint Tech., Ltd. v. F.C.C.*,  
412 F.3d 145 (D.C. Cir. 2005) .....16

*Palomar Medical Center v. Sebelius*  
693 F.3d 1151 (9th Cir. 2012) .....43, 44

*Peter Pan Bus Lines, Inc. v. Fed. Motor Carrier Safety Admin.*,  
471 F.3d 1350 (D.C. Cir. 2006) .....17

*Petit v. U.S. Dept. of Educ.*,  
675 F.3d 769 (D.C. Cir. 2012) .....25

*\*Randolph–Sheppard Vendors of Am. v. Weinberger*,  
795 F.2d 90 (D.C.Cir.1986) .....33, 34, 36, 40

*Ryan v. Bentsen*,  
12 F.3d 245 (D.C. Cir. 1993) .....29

*Shalala v. Illinois Council on Long Term Care, Inc.*,  
529 U.S. 1 (2000).....3, 28, 44, 45

*Shays v. Federal Election Comm’n*,  
528 F.3d 914 (D.C. Cir. 2008) .....13

*Summit Petroleum Corp. v. U.S. E.P.A.*,  
690 F.3d 733 (6th Cir. 2012) .....16

*Swegan v. Shepherd of the Valley Lutheran Retirement Servs, Inc.*,  
2013 WL 1284309 (N.D. Ohio 2013) .....12

*\*Tataranowicz v. Sullivan*,  
753 F. Supp. 978 (D.D.C. 1990), *rev’d on other grounds*, 959 F.2d 268 (D.C. Cir.  
1992) .....32, 36, 39

*\*Tataranowicz v. Sullivan*,  
959 F.2d 268 (D.C. Cir. 1992) ..... passim

*Thompson v. Clark*,  
741 F.2d 401, 409 (D.C. Cir. 1984) .....28

*U.S. ex rel. Hobbs v. MedQuest Assocs., Inc.*,  
711 F.3d 707 (6th Cir. 2013) .....27

*U.S. Women’s Chamber of Commerce v. U.S. Small Bus. Admin.*,  
2005 WL 3244182 (D.D.C. Nov. 30, 2005) .....10

*Urban Health Care Coal. v. Sebelius*,  
853 F. Supp. 2d 101 (D.D.C. 2012) .....36

*Village of Barrington, Ill. v. Surface Transp. Bd.*,  
636 F.3d 650 (D.C. Cir. 2011) .....17, 18

*Washington Hosp. Ctr. v. Bowen*,  
795 F.2d 139 (D.C. Cir. 1986) .....26

**FEDERAL STATUTES**

5 U.S.C. § 706(2)(A), (D) .....10

28 U.S.C. § 1331 .....44, 45

42 U.S.C. § 405 .....3

42 U.S.C. § 1395d(a) .....5, 16

42 U.S.C. § 1395f .....24, 25

42 U.S.C. § 1395k(a) .....7

42 U.S.C. § 1395n(a) .....8, 20

Pub. L. No. 89-97, § 102(a), 79 Stat. 286, 294 .....25

Pub. L. No. 90-248, § 126(a), 81 Stat. 921, 846 .....25

Pub. L. 106-554 § 521, 114 Stat. 2763A-534 .....23

Pub. L. 108-173 § 911, 117 Stat. 2378 .....23

**FEDERAL REGULATIONS**

42 C.F.R. §§ 405.926(l), 405.926(n), 405.968(b)(1), 405.980(a), 405.982(a), 405.1063,  
412.3(a)-(c), 412.3(e), 414.5, 424.13, 424.44(b), 440.2(a)(2), 482.1, 482.12(c)(2),  
482.24(c), 488.28, 488.3, 488.20, 488.26, and 488.28

72 Fed. Reg. 66,579, 66,814 (Nov. 27, 2007) .....15

78 Fed. Reg. 16,632, 16,639–40 (Mar. 18, 2013) .....8

78 Fed. Reg. 50,496, 50,953 (Aug. 19, 2013) .....5

79 Fed. Reg. 90,416 (July 14, 2014) .....38

**RULES**

Fed. R. Civ. P 15 .....30, 44

Fed. R. Civ. P. 56(a) .....9

Fed. R. Civ. Proc. 12(b)(1) .....10, 30

**OTHER AUTHORITIES**

AHA, Exploring the Impact of the RAC Program on Hospitals Nationwide: RACTrac Survey Results for 1st Quarter 2014 (May 28, 2014), *available at* <http://www.aha.org/content/14/14q1ractracresults.pdf>.....21

Cambridge Dictionaries Online, “Inpatient,” *available at* <http://dictionary.cambridge.org/us/dictionary/american-english/inpatient?q=inpatient>..... 11

Cambridge Dictionaries Online, “Outpatient,” *available at* <http://dictionary.cambridge.org/us/dictionary/american-english/outpatient?q=outpatient>..... 11

Collins Dictionary, “Inpatient,” *available at* <http://www.collinsdictionary.com/dictionary/english/inpatient?showCookiePolicy=true> ..... 11

CMS, FY 2014 Final Rule Tables – Table 5, *available at* <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2014-IPPS-Final-Rule-Home-Page.html> (click on “FY 2014 Final Rule Tables” and download the “Table 5” file)..... 13

CMS, Medicare Fee-for-Service Recovery Audit Program Myths (Dec. 17, 2012), *available at* <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Downloads/RAC-Program-Myths-12-18-12.pdf>. ....22

CMS, Selecting Hospital Claims for Patient Status Reviews, at 1-2 (Feb. 24, 2014), *available at* <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/Downloads/SelectingHospitalClaimsForAdmissionsForPosting02242014.pdf>.....34

H.R. Rep. No. 90-544 (1967).....25

*In re: Hendrick Med. Ctr.*,  
2012 WL 2324891 (DAB Apr. 23, 2012).....19, 43

*In re: UMDNJ-Univ. Hosp.*,  
2005 WL 6290383 (DAB Mar. 14, 2005).....19, 20, 43

Letter from Linda Fishman to Jonathan Blum (Sept. 18, 2013), AHA – Advocacy Issues, *available at* <http://www.aha.org/advocacy-issues/letter/2013/130918-cl-2midnight.pdf>.....33

Medicare Claims Processing Manual, Pub. No. 100-4, ch. 1 §§ 130.1, 130.2, ch. 3 §§ 50.1, 50.2, ch. 26, ch. 34 § 10.9 (Oct. 1, 2003), *available at* <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-> .....20, 43

Merriam-Webster Online, “Inpatient,” *available at* <http://www.merriam-webster.com/dictionary/inpatient>.....11

Merriam-Webster Online, “Outpatient,” *available at* <http://www.merriam-webster.com/dictionary/outpatient>.....11

Office of Medicare Hearings & Appeals, Adjudication Timeframes, *available at* [http://www.hhs.gov/omha/important\\_notice\\_regarding\\_adjudication\\_timeframes.html](http://www.hhs.gov/omha/important_notice_regarding_adjudication_timeframes.html) .....35

Office of Medicare Hearings & Appeals, Medicare Appellant Forum Presentation 108 (Feb. 12, 2014), *available at* [http://www.hhs.gov/omha/omha\\_medicare\\_appellant\\_forum\\_presentations.pdf](http://www.hhs.gov/omha/omha_medicare_appellant_forum_presentations.pdf) .....35

RAC Statement of Work 36, *available at* <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program/downloads/090111RACFinSOW.pdf>.....19

Statement of N. Griswold before U.S. House Committee on Oversight and Government Reform, Subcommittee on Energy Policy, Health Care & Entitlements (July 10, 2014), <http://oversight.house.gov/wp-content/uploads/2014/07/CMS-Griswold-OMHA-Final.pdf> .....35

S. Rep. No. 90-744 (1967).....25

## INTRODUCTION

Plaintiffs the American Hospital Association, Banner Health, Mount Sinai Hospital, Albert Einstein Healthcare Network, Wake Forest University Baptist Medical Center, Greater New York Hospital Association, Healthcare Association of New York State, New Jersey Hospital Association, and The Hospital & Healthsystem Association of Pennsylvania bring this action to challenge three unlawful Medicare policies. The policies impose arbitrary standards on hospitals across the country and deprive them of Medicare payments to which they are entitled. Plaintiffs seek an order vacating the three policies and a declaratory judgment that they are unlawful under the Administrative Procedure Act (“APA”) and the Medicare Act.

The three policies at issue were adopted together in August 2013, when the Secretary of Health and Human Services (“Secretary”), acting through the Centers for Medicare & Medicaid Services (“CMS”), promulgated final regulations governing Medicare payments to hospitals.

*First*, the Secretary adopted a new definition of the word “inpatient”—a word used repeatedly in the Medicare Act and a critical designation for purposes of Medicare reimbursement. Under Defendant’s novel definition, a person is an “inpatient” only if the admitting physician expects him to require hospital care for a period spanning “two midnights.” That is, the physician must expect that a patient who arrives on Day 1 will stay in the hospital that day, overnight, all the next day, into the next night, and will not be discharged until the early morning of Day 3. That definition flies in the face of plain meaning. The word “inpatient” has a well-established meaning—a person who remains in the hospital for at least *one* night—and Defendant has long hewed to it. The Secretary has offered no reasonable explanation for inventing a new definition now. Nor could she, for the sudden about-face appears to be nothing more than an effort to take money from hospitals: the Secretary must pay hospitals more for

treating inpatients, so the fewer of them there are the better it is for the bottom line. But the desire to cut costs hardly gives the Secretary license to re-write the dictionary. The new definition of “inpatient” is arbitrary and capricious and thus invalid under the APA.

*Second*, the Secretary devised another way to avoid reimbursing hospitals for the care they provide: She imposed a deadline on certain Medicare payment requests that is literally impossible to meet. When a hospital treats a Medicare beneficiary as an inpatient, it seeks payment under Medicare Part A. In some cases, however, a Medicare “review contractor” later reviews the cold paper record and determines that the patient should have been an outpatient. CMS then claws back the Part A payment. The Secretary has agreed that, when that happens, the hospital has a statutory entitlement to be paid under Part B, which covers *outpatient* services. After all, the treatment was proper; the only question is how the patient should be classified. And yet the Secretary now has foreclosed hospitals from obtaining that payment. She has done so by requiring hospitals to submit new Part B payment claims after a clawback and applying a one-year time limit to such claims, running from the date the hospital provided care, *even though the contractors almost never begin their review until more than a year after that date*. In other words, the time limit already has expired on the first day a hospital could seek Part B payment.

The Secretary does not have to require the submission of a new claim or apply a one-year limit, as we explain below. She has done so nevertheless, ensuring that hospitals will receive no payment whatsoever for many millions of dollars’ worth of care she agrees was medically necessary. That choice is arbitrary and capricious and thus invalid under the APA.

*Third*, the Secretary added a requirement that a written physician order be included in the patient’s medical record as a condition of Medicare payment for every inpatient stay. That is directly contrary to the Medicare statute: Congress amended the statute in 1967 to make clear

that a physician order is *not* required for Part A payment for short-term hospital stays. The requirement thus violates federal law. And as explained below, it bears no relationship to patient safety or any other worthy goal; instead, it serves only as a paperwork “gotcha” that allows Medicare to refuse to pay for care hospitals have provided.

Rather than defend any of these policies on their merits, the Secretary has moved to dismiss, claiming that this Court lacks jurisdiction because the hospital Plaintiffs have not exhausted their administrative remedies. That assertion is incorrect. The Medicare Act’s jurisdictional requirement is that litigants *present* their claims to the agency, *see Mathews v. Eldridge*, 424 U.S. 319, 328–30 (1976), and the Plaintiffs have done so many times over. The separate requirement that plaintiffs *exhaust* those remedies, by contrast, is waivable (though one would not know it from the Secretary’s brief, which conspicuously ignores the waiver doctrine). And this is a textbook waiver case. Waiver is appropriate where exhaustion would be futile because there is “no reason to believe that agency machinery might accede to plaintiffs’ claims.” *Tataranowicz v. Sullivan*, 959 F.2d 268, 274 (D.C. Cir. 1992). So it is here: Plaintiffs are challenging the validity of system-wide rules adopted by the Secretary after notice-and-comment rulemaking, and CMS’s administrative adjudicators are not at liberty to reject those rules. Nor are any particularized facts in dispute; these challenges are purely legal. This Court should waive exhaustion, as it has in similar circumstances before.

Moreover, with respect to the one-year time limit challenge, Plaintiffs need not—and indeed cannot—exhaust their administrative remedies at all. To be sure, 42 U.S.C. § 405 typically precludes federal question jurisdiction over Medicare claims and channels those cases through the administrative appeals process first. But the channeling requirement does not apply where it would mean “no review at all.” *Shalala v. Illinois Council on Long Term Care, Inc.*,

529 U.S. 1, 19 (2000); *Council for Urological Interests v. Sebelius*, 668 F.3d 704, 712 (D.C. Cir. 2011). That is the situation here. Medicare regulations provide that claim rejections based on the one-year time limit cannot be litigated through the administrative appeals process. 42 C.F.R. § 405.926(n). Thus, there is no way to funnel a legal challenge to the one-year time limit through the administrative process and into court; the administrative process is a brick wall. In those circumstances, the Supreme Court is clear that courts have federal question jurisdiction. If they did not, then no one would *ever* be able to challenge this rule of general applicability; it would be forever immune to review. That is not the law.

The Secretary's other arguments for dismissal are similarly baseless. She argues that Plaintiffs lack standing to challenge the physician-order requirement and the one-year time limit policy. But the physician-order requirement is being enforced now through the Medicare claims-payment process, and the Secretary has denied the Plaintiff hospitals reimbursement as a result. Likewise, the one-year time limit policy is subjecting Plaintiffs to both present and imminent injury, as described below. The Secretary also argues that Plaintiffs' challenge to the physician-order rule is not ripe because the subject is included in a new proposed rule that she announced days before the motion to dismiss in this case was filed. But that proposed rule has no bearing on the harm hospitals already have suffered under the *current* rule.

\* \* \*

While the Secretary purports to be puzzled by the "thread tying Plaintiffs' claims together," Def. Mem. 1, that thread is obvious to the nation's hospitals: For years now, she has been adopting policies that unlawfully shortchange hospitals and then striving to insulate those policies from judicial review. The Secretary's policy choices must be subject to the rule of law. Her motion to dismiss should be denied and Plaintiffs' motion for summary judgment granted.

## FACTUAL BACKGROUND<sup>1</sup>

**Medicare.** The Medicare program is divided into four parts, A through D. Parts A and B are the only ones relevant to this proceeding. Part A provides for reimbursement of “inpatient hospital services.” 42 U.S.C. § 1395d(a). Part B pays for various “medical and other health services” not covered by Part A, including hospital outpatient services. *Id.* § 1395k(a).

The question whether Part A or B will cover a beneficiary’s treatment often turns on whether the beneficiary is an “inpatient.” Indeed, the word “inpatient” appears 370 times in the Medicare Act alone. And the difference between payment under Part A and Part B is financially significant, both to hospitals and the Secretary, because Part A generally provides a hospital with more reimbursement. *See* 78 Fed. Reg. 50,496, 50,953 (Aug. 19, 2013). The difference also matters to beneficiaries because in many cases, beneficiaries classified as outpatients will have to pay significantly more out of pocket; for example, the Part B deductible, copayments for *each* hospital visit, items and services furnished during that visit, and certain prescription drugs. *See id.* at 50,907, 50,920-21.

**Definition of “Inpatient.”** The Medicare Act does not define “inpatient.” But Defendant has longstanding guidance on what “inpatient” means—guidance that, as set forth in more detail *infra* at 11, conforms to the word’s plain meaning. That guidance, published in a CMS policy manual, recognizes that whether a beneficiary should be admitted as an inpatient is best left to a physician’s judgment. Medicare Benefit Policy Manual (MBPM) ch. 1 § 10. But it also states that “generally, a patient is considered an inpatient if formally admitted as inpatient

---

<sup>1</sup> Plaintiffs have not attached a statement of undisputed facts because “[i]n cases where judicial review is based solely on the administrative record . . . a Statement of Undisputed Facts is not required.” *Grunewalv v. Jarvis*, 930 F. Supp. 2d 73, 81 n.2 (D.D.C. 2013). Rather, the parties cite to the administrative record. *Deppenbrook v. Pension Ben. Guar. Corp.*, 950 F. Supp. 2d 68, 71 n.2 (D.D.C. 2013) (Walton, J.). Because Defendant has not yet filed the administrative record, Plaintiffs cite to administrative-record documents directly.

with the expectation that he or she will remain at least *overnight*” and occupy a bed. 78 Fed. Reg. at 50,907 (citing MBPM ch. 1 § 10) (emphasis added). As discussed below, this comports with dictionary and case law definitions of the term. Defendant thus advised that physicians should “use a 24-hour period as a benchmark” and “order admission for patients who are expected to need hospital care for 24 hours or overnight, or more.” *Id.*

**The Final Rule and a New Definition of “Inpatient.”** The Secretary has now scrapped her longstanding definition. In August 2013, she issued a final rule governing payment to hospitals for inpatient services for fiscal year 2014. *See id.* at 50,496, 50,505–06 (Aug. 19, 2013) (“Final Rule”). In that document, she established a new rule for determining whether a patient is an inpatient for purposes of Part A payment: A beneficiary is an inpatient only if the physician expects him to require a stay that crosses “2 midnights”—that is, when the patient was admitted on day one and stayed in the hospital that night, the next day, and the next evening until at least midnight. *Id.* at 50,908, 50,965 (codified at 42 C.F.R. § 412.3(e)(1)).

Under this new rule, patients are not inpatients unless they are expected to stay in the hospital for longer—often much longer—than before. Take, for example, a beneficiary who arrives at the emergency room at 4 a.m. on Tuesday in need of surgery. After the procedure, she is moved to a hospital bed, spends that night and all the next day in the bed recovering, receives nursing services, medications and three or four meals, and is discharged at 6 p.m. on Wednesday. That patient spent well over 36 hours at the hospital, including a full night, and was an “inpatient” under any traditional understanding of that word. And yet, if the physician expected the patient to be discharged at 6 p.m. on Wednesday, she would *not* be an “inpatient” under the new rule. She would be an outpatient, because her stay did not cross “2 midnights.”

**The One-Year Time Limit.** The Final Rule also promulgated a new policy regarding

when, and how, hospitals can obtain payment under Medicare Part B after a Part A clawback. *See* 78 Fed. Reg. at 50,909. As discussed *supra* at 2, when a Medicare beneficiary is admitted to the hospital as an inpatient, the hospital seeks reimbursement under Part A for the care it provides. In some cases, however, a CMS contractor —typically a Recovery Audit Contractor, or “RAC” —later reviews that patient’s records and overrules the physician’s admission decision, determining that the treatment was reasonable but that the patient should have been classified as an “outpatient.” CMS then chooses to claw back the entire Part A payment.

The question is what happens next: Is the hospital left with no payment for care everyone agrees was reasonable and necessary? In the Final Rule, the Secretary recognized the answer should be no. *Id.* She acknowledged that the Medicare statute requires payment to hospitals under Part B for reasonable and necessary services they provide in these circumstances where the beneficiary has now been determined an “outpatient.” *Id.*; *see* 42 U.S.C. § 1395k(a). She accordingly wrote that when a Medicare contractor deems Part A payment unavailable because a patient should have been an outpatient, the hospital may rebill under Part B for all the services that would have been “reasonable and necessary” had the patient in fact been treated as an outpatient. 78 Fed. Reg. at 50,909; *see* 42 C.F.R. § 414.5.

Yet at the same time, the Secretary adopted another policy that effectively negates that legal entitlement and leaves hospitals with nothing. The Secretary chose to treat the rebilled Part B claims as separate “new claims,” even though the hospital is seeking reimbursement for the same treatment, of the same patient, as on the original Part A claim. 78 Fed. Reg. at 50,922. And she determined to apply the statute’s one-year time limit<sup>2</sup> to these “new” claims, thus

---

<sup>2</sup> Hospitals generally must submit reimbursement claims “no later than the close of the period ending 1 calendar year after the date of service.” 42 U.S.C. § 1395n(a)(1). However, that limit

requiring that they be filed within a year of the date the hospital provided care to the patient. *Id.*

That approach makes obtaining Part B payment impossible in nearly every case, because—as the Secretary knows—Medicare review contractors almost never even *begin* their review of a paid Part A claim until at least one year after the date of care. Thus the rebilled Part B claims would already be untimely on the first day the hospitals could submit them.

The Secretary proposed this impossible deadline in her Notice of Proposed Rulemaking, *see* 78 Fed. Reg. 16,632, 16,639–40 (Mar. 18, 2013), and the reaction was strong and swift: “Over 300 commenters” objected, while only “[o]ne commenter supported the proposal.” *Id.* at 50,922. Commenters pointed out that the policy would leave “few, if any, of a hospital’s denied Part A claims eligible for rebilling.” *Id.* at 50,923. And they observed that the Secretary could choose any number of alternative policies that would not withhold payments to which she herself says hospitals are entitled. *Id.* at 50,924–27. For example, the Secretary could treat the Part B bill as an adjustment to the original timely-filed Part A claim, which would not trigger the one-year time limit in the first place. *Id.* at 50,924. Or the Secretary could waive the one-year limit and require hospitals to rebill under Part B within a certain number of days. *Id.*

The Secretary rejected all alternatives and sided with the one over the 300. *Id.* at 50,922. She thus adopted a policy that ensures hospitals will receive no payment whatsoever for millions of dollars’ worth of care that everyone agrees was reasonable and medically necessary.

**The Physician-Order Rule.** The Secretary also promulgated a third new policy requiring that each patient’s record contain a written physician order admitting him as an inpatient. *See id.* at 50,965 (codified in 42 C.F.R. § 412.3(a)-(c)). That is now a condition of Part A payment. 42 C.F.R. § 412.3(c).

---

applies only to separate claims, not adjustments to existing claims. Moreover, “the Secretary may specify exceptions,” *id.*, and CMS has done so for a number of circumstances. *Infra* at 13.

When the Secretary proposed this physician-order rule, commenters objected for a number of reasons. They pointed out that the rule is contrary to the Medicare Act’s text and unusually explicit legislative history, both of which make clear that a physician certification is required only for longer-term hospital stays. 78 Fed. Reg. at 50,938-39. They also argued that the rule is duplicative because Medicare’s conditions of participation already require that inpatient admission decisions be made upon the “recommendation” of a physician. *Id.* And they pointed out that making the physician order a condition of payment carries with it a troubling side effect: A hospital’s failure to document a physician order could create the basis for liability under the False Claims Act (“FCA”). *Id.* In response, the Secretary brushed off the legislative history, ignored the commenters’ other concerns, and adopted the requirement anyway. *Id.*

### STANDARD OF REVIEW

**Summary Judgment.** Summary judgment is appropriate “if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). “In a case involving review of a final agency action” under the APA, however, the Rule 56 standard “does not apply because of the limited role of a court in reviewing the administrative record.” *Hosp. of Univ. of Pa. v. Sebelius*, 847 F. Supp. 2d 125, 133 (D.D.C. 2012). Instead, “[s]ummary judgment . . . serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review.” *Id.*; *Kaiser Found. Hosps. v. Sebelius*, 828 F. Supp. 2d 193, 198 (D.D.C. 2011), *aff’d*, 708 F.3d 226 (D.C. Cir. 2013). Under the APA, courts must “hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law,” or that are adopted “without observance of procedure required by law.” 5 U.S.C. § 706(2)(A), (D).

**Motion to Dismiss.** The Secretary bases her motion to dismiss on Fed. R. Civ. Proc. 12(b)(1). Under Rule 12(b)(1), the Court ““must accept as true all of the factual allegations contained in the complaint’ and draw all reasonable inferences in favor of the plaintiff[.]” *Evans v. First Mount Vernon, ILA*, 786 F. Supp. 2d 347, 351 (D.D.C. 2011) (citation omitted). The Court ““may consider such materials outside the pleadings as it deems appropriate to resolve the question whether it has jurisdiction[.]” *U.S. Women’s Chamber of Commerce v. U.S. Small Bus. Admin.*, 2005 WL 3244182, at \*3 (D.D.C. Nov. 30, 2005) (internal quotations omitted).

## ARGUMENT

### I. PLAINTIFFS ARE ENTITLED TO SUMMARY JUDGMENT.

Rather than dismiss this case, *see infra* at 28-45, the Court should enter judgment in Plaintiffs’ favor on each of the three issues presented. The Secretary’s new definition of the term “inpatient” is arbitrary and capricious because it bears no resemblance to the word’s plain meaning. The one-year time limit on rebilling is arbitrary and capricious because it makes it impossible for hospitals to obtain the Part B payments to which the Secretary herself says they are entitled and which hospitals need to provide patient care. And the Secretary’s physician-order rule is flatly contrary to a federal statute. Each of these policies should be vacated.

#### A. The Two-Midnight Rule Is Arbitrary and Capricious.

Under the Secretary’s new rule, a beneficiary is an “inpatient” only when the physician expects the patient to require a hospital stay that crosses “2 midnights”—a definition that, as explained *supra* at 6, means patients often will not be “inpatients” unless they are expected to stay in the hospital into the beginning of a third day. *Id.* That definition is arbitrary and capricious for at least two reasons: It bears no resemblance to the word’s actual meaning, and the Secretary made no attempt to explain why she adopted such an illogical definition.

1. Dictionaries consistently define “inpatient” as hospitals always have understood

it: a patient who stays *overnight* in a hospital for treatment. See Merriam-Webster Online, “Inpatient,” available at <http://www.merriam-webster.com/dictionary/inpatient> (“inpatient” is “a patient who stays for one or more nights in a hospital for treatment” or “a hospital patient who receives lodging and food as well as treatment”); Cambridge Dictionaries Online, “Inpatient,” available at <http://dictionary.cambridge.org/us/dictionary/american-english/inpatient?q=inpatient> (“a person who stays one or more nights in a hospital in order to receive medical care”); Collins Dictionary, “Inpatient,” available at <http://www.collinsdictionary.com/dictionary/english/inpatient?showCookiePolicy=true> (“a hospital patient who occupies a bed for at least one night in the course of treatment, examination, or observation”). An outpatient, by contrast, is “a patient who is *not* hospitalized overnight but who visits a hospital, clinic, or associated facility for diagnosis or treatment.” Merriam-Webster Online, “Outpatient,” available at <http://www.merriam-webster.com/dictionary/outpatient> (emphasis added); see also Cambridge Dictionaries Online, “Outpatient,” available at <http://dictionary.cambridge.org/us/dictionary/american-english/outpatient?q=outpatient> (“outpatient” is “a person who receives medical care from a hospital but who does not stay in the hospital for one or more nights”); Collins Dictionary, “Outpatient,” available at [http://www.collinsdictionary.com/dictionary/english/outpatient#outpatient\\_1](http://www.collinsdictionary.com/dictionary/english/outpatient#outpatient_1) (defining “outpatient” as “a nonresident hospital patient” or “someone who receives treatment at a hospital but does not spend the night there”).

Every other available definitional source—judicial decisions, other agencies’ regulations, even the Secretary’s own regulations for the Medicaid program—expresses precisely the same understanding of “inpatient.” The Supreme Court, for example, has “define[d] an inpatient as one admitted to the hospital for at least overnight bed occupancy.” *Abbott Labs. v. Portland Retail Druggists Ass’n, Inc.*, 425 U.S. 1, 9 (1976). The D.C. Circuit has explained that “inpatient

hospital services” generally refers to services provided during “overnight stays in a hospital.” *Catholic Health Initiatives Iowa Corp. v. Sebelius*, 718 F.3d 914, 916 (D.C. Cir. 2013). Federal courts have recognized that under Department of Labor regulations, “inpatient” is defined as “ ‘an overnight stay in a hospital, hospice or residential medical care facility.’ ” *Bonkowski v. Oberg Indus., Inc.*, --- F.Supp.2d ----, 2014 WL 199790, at \*9 (W.D. Pa. 2014) (quoting 29 C.F.R. § 825.114); accord, e.g., *Swegan v. Shepherd of the Valley Lutheran Retirement Servs, Inc.*, 2013 WL 1284309, at \*4 (N.D. Ohio 2013). State courts have reached the same conclusion. See, e.g., *Methodist Hosps., Inc. v. Lake Cnty. Property Tax Assessment Bd. of Appeals*, 862 N.E.2d 335, 339 (2007); *Abbott-Northwestern Hosp. v. C.I.R.*, 1996 WL 438847, at \*2 (Minn. Tax 1996).

Even the Secretary herself, in defining covered services under Medicaid, has long used a 24-hour period as the dividing line between “inpatient” and “outpatient.” Her Medicaid regulations have since 1987 defined “inpatient” as a patient admitted to a “medical institution” (which includes a hospital) and who “receives room, board and professional services in the institution for a 24 hour period or longer” or “[i]s expected by the institution to receive room, board and professional services for a 24 hour period or longer[.]” 42 C.F.R. § 440.2(a)(2). By contrast, “outpatient means a patient of an organized medical facility . . . who is expected by the facility to receive and who does receive professional services for less than a 24-hour period.” *Id.*

2. This list could go on, but the point is clear: It has always and universally been understood that someone who stays overnight in a hospital bed for treatment is an “inpatient.” Until now, that is. The Secretary has now announced that the word inpatient has a very different meaning: a patient who spends *two* nights in the hospital. 78 Fed. Reg. at 50,908, 50,949, 50,965. And she has done so for a very simple reason: to save money.

The Secretary’s re-imagining of the word makes it harder to become an “inpatient”—a longer expected stay is now required—and thus will convert tens of thousands of inpatient cases, reimbursed under Part A, into outpatient cases, reimbursed under Part B at lower rates. Medicare claims data show that a variety of diseases and conditions—heart attacks, atherosclerosis, circulatory system problems, concussions, comas without complications, to name a few—are routinely treated on an inpatient basis for a period lasting less than two midnights. *See* CMS, FY 2014 Final Rule Tables, Table 5.<sup>3</sup> Similarly, many surgeries, such as appendectomies and mastectomies, routinely are performed on an inpatient basis for a period lasting less than two midnights. *See id.* For decades, physicians have determined that many of these patients should be admitted as inpatients. And CMS has agreed, creating Part A payment amounts and codes to provide inpatient payment for those services. And yet, these patients will no longer be “inpatients” under the new rule. Hospitals will be forced to bill Medicare as if these individuals were outpatients and will receive less reimbursement for treating those patients as a result.<sup>4</sup>

3. The Secretary’s new definition of inpatient is arbitrary and capricious because it bears no relationship to the word’s plain meaning. *See Shays v. Federal Election Comm’n*, 528 F.3d 914, 931 (D.C. Cir. 2008) (agency effort to define statutory term “get-out-the-vote activity” to include only individualized outreach, not robocalls, likely could not “even survive at *Chevron* step one, for we doubt whether the meaning of GOTV activity . . . can plausibly be limited to

---

<sup>3</sup> Available at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2014-IPPS-Final-Rule-Home-Page.html> (click on “FY 2014 Final Rule Tables” and download the “Table 5” file).

<sup>4</sup> The Secretary claimed in the Final Rule, counter-intuitively and without explanation, that the two-midnights rule somehow would result in a net *increase* in inpatient cases, and thus would increase the total amount paid for inpatient care. 78 Fed. Reg. at 50,952–54. And she used that assertion as cover to reduce Part A reimbursement to hospitals. *See id.* at 50,943. The Secretary’s illogical assertion and payment cut are the subject of a separate lawsuit.

individualized assistance”); *Harbert v. Healthcare Servs. Group, Inc.*, 391 F.3d 1140, 1148-49 (10th Cir. 2004) (agency’s definition of “worksites” as central office where the employee reports, instead of site where the employee actually does work, invalidated as arbitrary and capricious because it “contravenes the plain meaning of the term”); *Dabertin v. HCR Manor Care, Inc.*, 373 F.3d 822, 829 (7th Cir. 2004) (defendant’s definition of “scope” was arbitrary and capricious because it “defied common sense and was not in accord with the ordinary and popular meaning of the term”). As the cited cases demonstrate, the Secretary cannot just redefine commonly-understood terms to save money. Indeed, if she were free to change the meaning of “inpatient” from “one night in the hospital” to “two nights in the hospital,” where is the stopping point? Three days? A week? The Secretary has some latitude to define undefined statutory terms, but she cannot abandon their plain meaning altogether. Just as in *Harbert*, the new definition of inpatient “contravenes the plain meaning of the term.” 391 F.3d at 1148-49. It cannot stand.<sup>5</sup>

4. At the very least, if the Secretary seeks to deviate from common meaning in this way, she is obliged to explain why that makes sense. *See, e.g., Am. Petroleum Inst. v. Johnson*, 541 F. Supp. 2d 165, 173 (D.D.C. 2008) (vacating regulatory definition where “EPA violated the APA by failing to provide a sufficiently clear, cogent and reasoned explanation for its decision to promulgate such a broad definition of ‘navigable waters’”). Here, the Secretary not only failed to provide a “sufficiently clear” explanation, *id.*; she failed to provide any explanation at all.

That failure violates the APA and requires the vacatur of the Secretary’s new definition.

But on a less technical level, it also amounts to an abdication of her responsibility to the hospitals

---

<sup>5</sup> The government writes that the rule merely changes the “benchmark” for inpatient admissions “from a 24-hour period to a single calendar day, measured midnight to midnight.” Def. Mem. 1, 4. This suggestion that the change is semantic is risible. By definition, a stay that crosses two midnights cannot be “a single calendar day;” it must cross three calendar days. Moreover, because people generally do not arrive at the hospital at 11:59 p.m., most patients will require expected hospitalization times far exceeding 24 hours before they can be classified as inpatients.

and patients affected by the agency's policies. That is so because the new rule will tangibly and adversely affect the healthcare system. It will cost hospitals many millions of dollars to which they are entitled for providing patient care. *See supra* at 8. Far worse, it has the potential to undercut appropriate patient care, according to the Secretary's own logic. A physician uncertain of a patient's diagnosis or how to treat a patient's symptoms—and thus uncertain whether the patient will need to stay in the hospital for “two midnights” —will order the patient to receive observation services as an outpatient. But the Secretary has said that she “do[es] not consider observation services and inpatient care to be the same level of care and, therefore, *they would not be interchangeable and appropriate for the same clinical scenario.*” 72 Fed. Reg. 66,579, 66,814 (Nov. 27, 2007) (emphasis added). Many commenters expressed exactly that concern during the rulemaking, explaining that “there are many beneficiaries who stay in a hospital for less than 2 midnights but still require an inpatient level of care.” *Id.* at 50,945. The Secretary dismissed those concerns and rejected suggestions that she should create any exceptions to her new time-based rule based on the level of care the patient needs—even in cases in which the beneficiary needs to be treated in an intensive care unit. *See id.* at 50,946.

That is unacceptable. If the Secretary is to flee from plain meaning in a way that affects the nation's hospitals and patient care, she must at least explain herself. She failed to do so.

Defendant's unreasoned policy is arbitrary and capricious under the APA.

5. The Secretary's definition of “inpatient” is properly analyzed using the arbitrary-and-capricious test because she purported to be establishing payment policy. *See, e.g., id.* at 50,949. But to the extent that definition should be analyzed under *Chevron*, the result is the same: It fails at step one because the plain meaning of “inpatient” forecloses the Secretary's interpretation, and alternatively it fails at step two because her construction is unreasonable and

unexplained. *See Chevron U.S.A. Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 844 (1984).

“[U]nder the *Chevron* two-step, we stop the music at step one if the Congress has directly spoken to the precise question at issue because we—and the agency—must give effect to [its] unambiguously expressed intent. . . . But if the statute is silent or ambiguous, we dance on and, at step two, defer to the Commission’s interpretation if it is based on a permissible construction of the statute.” *Northpoint Tech., Ltd. v. F.C.C.*, 412 F.3d 145, 151 (D.C. Cir. 2005) (internal citations and quotations omitted). Here, the Secretary trips at step one because her definition of “inpatient” contravenes Congress’s “unambiguously expressed intent.” *Id.* Congress chose to make eligibility for Part A payment for hospital stays turn on whether the beneficiary is an “inpatient.” *See, e.g.*, 42 U.S.C. § 1395d(a). And while Congress did not define “inpatient” as a standalone term, “[e]very undefined term . . . is not necessarily ambiguous.” *See Moreland v. United States*, 968 F.2d 655, 663 (8th Cir. 1992). “Inpatient” has a clear, common meaning: one who stays overnight in the hospital to receive treatment. *See supra* 11-12. The Secretary’s definition cannot be reconciled with that plain meaning. And where the “plain language” Congress chose “establishes [its] unambiguous intent,” the analysis is over: The agency’s interpretation fails “at *Chevron* step one.” *Hearth, Patio & Barbecue Ass’n v. U.S. Dep’t of Energy*, 706 F.3d 499, 506 (D.C. Cir. 2013). *See, e.g., Koch Foods, Inc. v. Sec’y, U.S. Dep’t of Labor*, 712 F.3d 476, 480 (11th Cir. 2013) (invalidating regulation at step one where dictionary definitions revealed that agency’s interpretation of the statutory word “because” contravened that word’s unambiguous plain meaning); *Summit Petroleum Corp. v. U.S. E.P.A.*, 690 F.3d 733, 741 (6th Cir. 2012) (invalidating EPA regulation at *Chevron* step one where dictionary definitions revealed that the agency’s interpretation of the term “adjacent” contravened the word’s unambiguous plain meaning).

paid for inpatient hospital services only if a physician certifies that “such services are or were required to be given on an inpatient basis[.]” Pub. L. No. 89-97, § 102(a), 79 Stat. 286, 294. Two years later, however, Congress amended the statute and struck the quoted language, replacing it with the current paragraph (3), which limits the certification requirement by adding the “over a period of time” qualifier. *See* Pub. L. No. 90-248, § 126(a), 81 Stat. 921, 846. And the legislative reports on that amendment explained, in no uncertain terms, why Congress made this change: to *eliminate* the requirement that a physician order appear in the files in every case. *See* H.R. Rep. No. 90-544, at 149 (1967); S. Rep. No. 90-744, at 239 (1967). Both the House and Senate reports state that the effect of the change was to “*eliminate the hospital insurance program requirement that there be a physician’s certification of medical necessity with respect to each admission to a general hospital, and to require such a certification only in cases of hospital stays of extended duration[.]*” *Id.* (emphasis added).

This history makes unmistakably clear that the language “furnished over a period of time” limits the physician-order requirement to extended inpatient stays. And that means the Secretary’s new rule—a rule that re-establishes the very requirement Congress deleted—fails at *Chevron* step one. “[A]t step one, a court must ‘exhaust the traditional tools of statutory construction to determine whether Congress has spoken to the precise question at issue. The traditional tools include examination of the statute’s text, legislative history, and structure, as well as its purpose.’ ” *Petit v. U.S. Dept. of Educ.*, 675 F.3d 769, 781 (D.C. Cir. 2012) (citation omitted). And here, the “text” and “legislative history” foreclose the Secretary’s interpretation so clearly that they almost seem written for the occasion. The rule accordingly cannot stand. As the D.C. Circuit has put it, the agency’s interpretation must be invalidated where it is “contrary to congressional intent as expressed in the plain language and legislative history” of the

The Court need not proceed to *Chevron* step two, but even if it did, the “two midnights” definition fails there too because it is not a permissible construction of the statute; it is just as unreasonable to change the meaning of “inpatient” from “one night” to “two nights” as it would be to change the meaning of “weekend” from two days to four. *See Hearth*, 706 F.3d at 507 (statutory term not quite clear enough, standing alone, to foreclose agency’s interpretation at step one was nonetheless unreasonable at step two); *Electric Power Supply Ass’n v. F.E.R.C.*, --- F.3d ---, 2014 WL 2142113 at \*5 (D.C. Cir. May 23, 2014) (“[E]ven if we assumed the statute was ambiguous . . . we would find FERC’s construction of it to be unreasonable for the same reasons we find the statute unambiguous.”). In addition, the Secretary failed even to assert that Congress’s intent was not plain from the statute’s face, or to use any of the tools of statutory construction that apply in the face of ambiguity, and thus her interpretation cannot be affirmed at step two in any event. *See Peter Pan Bus Lines, Inc. v. Fed. Motor Carrier Safety Admin.*, 471 F.3d 1350, 1354 (D.C. Cir. 2006) (“[D]eference to an agency’s interpretation of a statute is not appropriate when the agency wrongly believes that interpretation is compelled by Congress.”) (internal quotations omitted); *accord Village of Barrington, Ill. v. Surface Transp. Bd.*, 636 F.3d 650, 665 (D.C. Cir. 2011) (“At *Chevron* step two we defer to the agency’s permissible interpretation, but only if the agency has offered a reasoned explanation for why it chose that interpretation.”) (citation omitted). Under pure APA analysis or *Chevron* analysis, the result is the same: the Secretary’s interpretation of “inpatient” cannot stand.

**B. The Application of the One-Year Filing Rule to Rebilled Part B Claims Is Arbitrary and Capricious.**

The Secretary’s imposition of a one-year time limit on hospitals’ Part B “rebilling” requests likewise is arbitrary and capricious. It denies hospitals payments that even the Secretary says they are entitled to receive, and nothing in the law requires her to impose the time limit. On

those facts the decision to impose the time limit cannot withstand APA review.

1. The Secretary has acknowledged that where she claws back a Part A payment on the grounds that the patient should have been classified as an outpatient, hospitals are statutorily entitled to be paid for all Part B services that would have been reasonable and necessary if the hospital had treated the beneficiary as outpatient. *See supra* at 7. Yet by requiring hospitals to submit a new claim and imposing the one-year-time-limit policy, the Secretary has made it impossible for hospitals to obtain that payment in almost every case. *See id.* Given that nearly all Part A denials are issued by the contractors more than a year after the date the service was provided, hospitals' requests for Part B payment would be untimely even if filed on the same day the contractor issued its Part A denial. *See supra* at 8; *see also* 78 Fed. Reg. at 50,923.

2. Nothing in the Medicare statute or regulations requires the Secretary even to demand the submission of a new claim, let alone to apply the one-year time limit. The Secretary has several other feasible choices. Her decision to require a new claim and apply the time limit notwithstanding these alternatives is indefensible.

a. First, the Secretary need not require hospitals to "rebill" at all. Instead of denying the Part A claim and clawing back the entire amount, the Medicare contractors could simply adjust the claim themselves and take back only the *difference* between the Part A and Part B payment. That option fits within the established rules governing payment recovery where a Part A stay is denied on the ground that the patient should have been treated as an outpatient. To claw back the Part A payment, the contractor must reopen the originally paid Part A claim—known as the "initial determination"—and issue a revised initial determination that identifies the Part A payment as an "overpayment" and seeks to recover it. *See* 42 C.F.R. § 405.980(a). Once the claim is reopened, nothing prevents the contractor from offsetting the amount of Part B

reimbursement to which the hospital is entitled against the Part A overpayment and issuing a revised determination that seeks to recover only the difference. Indeed, the Secretary’s guidance to her contractors clearly *contemplates* that contractors will process “partial adjustments” to claims in a variety of circumstances—including in cases of “inpatient stays that should have been billed as outpatient.” RAC Statement of Work 36.<sup>6</sup> And a long line of decisions from HHS administrative judges and from Medicare’s highest appeals body, the Departmental Appeals Board Medicare Appeals Council (“DAB”), ordered contractors make payment under Part B after a Part A payment was denied and taken back. *See, e.g., In re: Hendrick Med. Ctr.*, 2012 WL 2324891, at \*5-6 (DAB Apr. 23, 2012); *In re: UMDNJ-Univ. Hosp.*, 2005 WL 6290383, at \*10 (DAB Mar. 14, 2005). As the DAB put it: “When the [contractor] reopened the determinations on the initial claims at issue here, it had the same plenary authority to process and adjudicate each claim as it did when that claim was first presented and paid.” *UMDNJ-Univ. Hosp.*, 2005 WL 6290383, at \*9. Thus there is no need for the Secretary to make hospitals submit a Part B claim, or request a second “reopening,” to obtain payment under Part B.

b. The Secretary also has a second, closely related, option: She easily can convert the original Part A claim to a request for Part B payment without deeming the rebilling a “new claim” and triggering the time limit. Medicare policy has long permitted hospitals to submit “adjustment bills” as the “most common mechanism for changing a previously accepted bill.” CMS, Medicare Claims Processing Manual (“MCPM”),<sup>7</sup> Pub. No. 100-4, ch. 1 §§ 130.1, 130.2 (Oct. 1, 2003); *see also id.* ch. 3 § 50 (Aug. 15, 2008); *id.* ch. 3 §§ 50.1, 50.2 (Oct. 1, 2003).

---

<sup>6</sup> Available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program/downloads/090111RACFinSOW.pdf>.

<sup>7</sup> Available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS018912.html?DLPAGE=1&DLSort=0&DLSortDir=ascending>.

HHS's ALJs and the DAB used adjustment billing to direct Medicare contractors to make payment under Part B after a Part A clawback, *see, e.g., UMDNJ-Univ. Hosp.*, 2005 WL 6290383, at \*9, and the Secretary acquiesced to that approach on a temporary basis as recently as last year. *See* 78 Fed. Reg. at 50,924. And it makes sense to do so: Hospitals in these cases are simply seeking payment for “the very same items and services” already “identified with specificity on the original Part A claim”; all Medicare needs is minor “supplementary information in order to process a Part B claim” for those same services. *UMDNJ-Univ. Hosp.*, 2005 WL 6290383, at \*9. Indeed, in most cases hospitals bill for the services provided to Medicare beneficiaries under Part A or Part B by completing the *same* electronic claim form (marked either as a Part A or a Part B “type of bill”) and submitting it through a single electronic processing system. *See generally* MCPM ch. 26.<sup>8</sup> Rebilled Part B claims are not new claims.

c. Third, even if the Secretary insists that hospitals submit “new” Part B claims, she has authority to create exceptions to the one-year time limit for filing claims, *see* 42 U.S.C. § 1395n(a), and has done so in analogous circumstances where “providers, suppliers, and beneficiaries, through no fault of their own, would be disadvantaged through strict application of the 1-calendar year” filing requirement.” 78 Fed. Reg. at 50,924; *see* 42 C.F.R. § 424.44(b).

That “no fault” rationale applies with equal force here because hospitals cannot avoid Part A denials under the unworkable two-midnights standard. Since the advent of RACs, inpatient stays have been regularly denied where—in hindsight and based on the cold paper record—the RACs simply disagreed with the physician’s judgment about the care the patient should have been expected to need at the hospital. And the RACs are frequently wrong:

---

<sup>8</sup>*Available at* <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c26.pdf>

Hospitals report that when they appeal denials by the RACs, those appeals are successful more than two-thirds of the time. AHA, *Exploring the Impact of the RAC Program on Hospitals Nationwide: RACTrac Survey Results for 1st Quarter 2014* (May 28, 2014), at 55.<sup>9</sup>

There is no reason to believe the RACs' unwillingness to accept physicians' admission decisions will change now that they must base their decisions on a "two midnight" expectation, instead of 24 hours. If anything, the problem will be worse: Given the many factors that affect length of stay, it is much harder to predict whether a patient will be in the hospital for two nights versus one, as even the Secretary has recognized. See 78 Fed. Reg. at 50,945. Take, for example, the requirement that a physician consider, as part of the inpatient admission analysis, the risk that a patient might experience an adverse event in the near term. See 42 C.F.R. § 412.3(e)(1). How can a physician accurately predict whether a patient is likely to develop complications or suffer a relapse over the course of the next 48 hours? And more to the point, how can a physician convey that risk through documentation in the patient's medical record, such that a RAC reviewing the medical record years later (without speaking to the admitting physician) will agree that the physician's assessment was reasonable?

The answer: There is no way to ensure that RACs won't reach the opposite conclusion, and thus no way to avoid Part A clawbacks altogether. That is true even assuming no thumb on the scale—and yet that assumption is dubious because the RACs have strong financial incentives to construe medical records unfavorably to the hospital. The RACs, after all, are paid a contingency fee based on each clawed-back Part A payment. See CMS, *Medicare Fee-for-Service Recovery Audit Program Myths* (Dec. 17, 2012) (RACs earn contingency fee percentage

---

<sup>9</sup> Available at <http://www.aha.org/content/14/14q1ractracresults.pdf>

between 9.0 and 12.5 percent).<sup>10</sup> It is hard to imagine, given that incentive, that RACs suddenly will start agreeing with admitting physicians' admission decisions across the board.

In short: Hospitals cannot avoid some RAC Part A clawbacks, no matter how carefully their admitting physicians hew to CMS's guidance. That is exactly the sort of "no fault" circumstance that led the Secretary to establish exceptions to the one-year deadline in the past.

3. Nevertheless, the Secretary elected to apply the one-year time limit in a way that ensures hospitals will receive no reimbursement for millions of dollars of care that all agree was reasonable and medically necessary—reimbursement the Secretary herself agrees that hospitals are entitled to receive. That is arbitrary and capricious because the Secretary made no serious attempt to explain why her deeply flawed choice was better than the available alternatives.

An agency must "articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made' " that must be "sufficient to enable [the court] to conclude that the [agency's action] was the product of reasoned decisionmaking." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43, 52 (1983). As a corollary, the agency must consider and explain its rejection of "significant and viable" and "obvious alternatives," especially when "the choice embraced suffers from noteworthy flaws." *City of Brookings Mun. Tel. Co. v. F.C.C.*, 822 F.2d 1153, 1169 (D.C. Cir. 1987).

The Secretary's attempt to explain her rejection of the alternatives described above, and others suggested by commenters, is wholly inadequate under these standards. For example, when rejecting commenters' suggestion that Medicare use adjustment billing to permit Part B

---

<sup>10</sup> Available at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Downloads/RAC-Program-Myths-12-18-12.pdf>.

payment without a “new” bill, the Secretary offered only the following: Adjustment billing is inappropriate because “the nature of the original claim is fundamentally changed from a Part A claim to a Part B claim.” *See* 78 Fed. Reg. at 50,924. That assertion makes little sense on its face—what does it mean to say a claim’s “nature” has changed when it is for the same patient and same services? —and was left wholly unexplained. Moreover, even assuming the Secretary’s assertion was something more than mere throwaway language, it does not hold up in the context of the current Medicare program. Although years ago Medicare Parts A and B were more like separate programs, administered through distinct types of contractors, Congress has since required the Secretary to streamline the two Parts, directing the Secretary to use the same contractors to pay both Part A and Part B claims and to implement a single appeals process for all claims. Medicare Modernization Act of 2003, Pub. L. 108-173 § 911, 117 Stat. 2378 (codified at 42 U.S.C. § 1395kk-1); *id.* § 931, 117 Stat. 2397; Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. 106-554 § 521, 114 Stat. 2763A-534 (codified at 42 U.S.C. § 1395ff). Hospitals bill for services under Part A or Part B using the same basic electronic form, and Part A and Part B claims are processed and paid by the same contractor. *See generally* MCPM ch. 26. And last but not least, the Secretary’s assertion directly contradicts her own instruction to the RACs to make partial adjustments in cases of “inpatient stays that should have been billed as outpatient.” RAC Statement of Work, *supra*, at 36. Defendant’s self-serving, unexplained, single-sentence, internally contradictory rejection of adjustment billing does not clear the APA’s bar.

As for commenters’ suggestion that the Secretary waive the one-year time limit and adopt a different time limit for rebilling Part B claims, Defendant rejected it on the ground that “[h]ospitals . . . have the ability to avoid being disadvantaged by the 1-calendar year time limit to

file claims and by any subsequent RAC audit if they bill correctly by following Medicare’s guidelines for hospital inpatient admissions.” 78 Fed. Reg. at 50,923. Indeed, the Secretary repeated that same explanation verbatim at least eight times. *See id.* at 50,923–27. But simply restating the same unfounded statement does not amount to a reasoned explanation of her choice. And here that explanation is *not* reasoned: It does not grapple with the fact, explained above, that it is quite impossible for hospitals to avoid all RAC clawbacks. RACs can—and regularly have—disagreed with physicians’ judgments based on a wholly discretionary re-weighing of the factors at issue. Commenters explained as much to the Secretary, *see id.* at 50,926, and she offered no plausible response. For this and all the reasons set forth above, the Secretary’s application of the one-year time limit is invalid under the APA.

**C. The Physician-Order Rule Violates the Medicare Act and the APA.**

The physician-order rule is unlawful for two separate reasons. First, it is in direct contravention of the Medicare Act and the APA. Second, though the Court need go no further, the rule also is arbitrary and capricious because the Secretary failed to provide any justification for it, despite the inherent risks of mandating physician orders as a condition of payment.

1. The Secretary relies on 42 U.S.C. § 1395f(a)(3) as authority for the physician-order rule. *See* 78 Fed. Reg. at 50,938. That provision and its history, however, foreclose the rule. Subsection 1395f(a)(3) provides that payment for Medicare services may be made only if:

*with respect to inpatient hospital services (other than inpatient psychiatric hospital services) which are furnished over a period of time, a physician certifies that such services are required to be given on an inpatient basis for such individual’s medical treatment[.]*

(emphases added.) The italicized language strongly suggests that a physician certification is required only for long inpatient stays. But the legislative history puts any doubt to rest. When Medicare was enacted in 1965, Subsection 1395f(2)(A) stated that an eligible provider could be

Medicare Act. *Washington Hosp. Ctr. v. Bowen*, 795 F.2d 139, 141 (D.C. Cir. 1986); accord *Georgetown University Hospital v. Bowen*, 821 F.2d 750, 758 (D.C. Cir. 1987) *aff'd*, 488 U.S. 204 (1988) (Secretary's actions were barred where it was "clear from the terms and the legislative history of the Medicare Act that Congress did *not* intend to empower the Secretary to promulgate retroactive cost-limit rules."). That is particularly obvious where, as here, "Congress has so explicitly and deliberately considered, and then rejected, a more expansive requirement[.]" *General Motors Corp. v. Ruckelshaus*, 742 F.2d 1561, 1578 (D.C. Cir. 1984). In such cases "it is not for the agency to exceed the statutory limits under the guise of 'interpretation.'" *Id.*

2. The Court need go no further, but we note that the physician-order rule is arbitrary and capricious even setting aside its clear invalidity under the statute's plain language. The Secretary did not provide any justification for creating this new condition of payment after more than 50 years of contrary policy. That failure to justify is a textbook APA violation. *See, e.g., Am. Petroleum*, 541 F. Supp. 2d at 182 (requirement of agency explanation "includes an obligation to explain a decision to depart from a 'settled course of behavior.'" (quoting *Int'l Ladies' Garment Workers' Union v. Donovan*, 722 F.2d 795, 813-15 (D.C. Cir. 1983))).

The Secretary's failure to provide an explanation is unsurprising, for what explanation could she offer? The physician-order rule does not serve to protect patient health or safety or to avoid a lack of clarity in record-keeping because regulations already require (as a condition of a hospital's participation in Medicare) that the inpatient admission decision be made upon the "recommendation" of a physician, 42 C.F.R. § 482.12(c)(2), and that the patient's medical record "contain information to justify admission and continued hospitalization," *id.* § 482.24(c).

But the problem is greater than redundancy: The rule threatens affirmative harm to

hospitals and patients by heightening the risk of FCA liability and potentially increasing the incidence of long observation stays. That is so because of the interaction between the physician-order rule and the two-midnights definition of “inpatient.” Taken together, those policies require physicians to predict a stay of more than two midnights, and *certify* that expectation, to justify admission in every case. 42 C.F.R. § 412.3(c), (e). That prediction is often impossible to make with confidence. *See supra* at 15. Faced with the uncertainty inherent in long-term predictions and the burden of Medicare review contractors’ widespread practice of second-guessing physician judgments, the message to physicians is clear: order outpatient observation services for as long as it takes to confirm, with certainty, that the patient requires hospitalization for two midnights. Thus, the physician-order rule undermines the Secretary’s own stated intent to reduce the occurrence of long observation stays. *See* 78 Fed. Reg. at 50,906-07.

That is bad for patients, since according to the Secretary herself, observation care in many circumstances is no replacement for inpatient admission. *See supra* at 15. But it also poses a substantial risk for hospitals because whistleblowers may use the new certification requirement to allege fraud or FCA liability. *See, e.g., U.S. ex rel. Hobbs v. MedQuest Assocs., Inc.*, 711 F.3d 707, 714 (6th Cir. 2013) (“A false-certification theory only applies where the underlying regulation is a ‘condition of payment[.]’”). To be sure, one incorrect prediction likely will not, in practice, give rise to an FCA claim. But doctors must make admissions decisions many times a day. An aggressive relator surely could attack a physician for multiple certified predictions that did not come to pass.

Despite these very real risks, the Secretary failed to provide any coherent justification for promulgating a rule that violates the Medicare Act. What is more, she never even responded to commenters’ concerns regarding FCA liability. That is unacceptable. “The requirement that

agency action not be arbitrary and capricious includes a requirement that the agency . . . respond to relevant and significant public comments.” *Cape Cod Hosp. v. Sebelius*, 630 F.3d 203, 211 (D.C. Cir. 2011). Indeed, an agency’s failure to respond to significant comments generally “ ‘demonstrates that the agency’s decision was not based on a consideration of the relevant factors,’ ” *Lilliputian Sys., Inc. v. Pipeline & Hazardous Materials Safety Admin.*, 741 F.3d 1309, 1313 (D.C. Cir. 2014) (quoting *Thompson v. Clark*, 741 F.2d 401, 409 (D.C. Cir. 1984)), and that the decision was arbitrary and capricious. The physician-order rule should be vacated.

## **II. THE GOVERNMENT’S MOTION TO DISMISS SHOULD BE DENIED.**

This Court has jurisdiction over Plaintiffs’ claims and dismissal is not warranted. For each of the three rules, Plaintiffs have presented their claims to the Secretary and exhaustion should be excused as futile. And, in the case of the one-year time limit, the channeling requirements do not even apply. Moreover, the Secretary’s standing and ripeness arguments collapse on examination. She has presented no reason to delay or foreclose judicial review.

### **A. This Court Has Jurisdiction Over Plaintiffs’ Two-Midnights Challenge.**

The Secretary argues that the Court lacks jurisdiction over Plaintiffs’ two-midnights challenge because they have not fully exhausted all four layers of CMS administrative review. But the Medicare Act requires as a jurisdictional prerequisite only that claimants present their claims to the agency. By contrast, the requirement that claimants exhaust administrative remedies is waivable. *Tataranowicz*, 959 F.2d at 272; *see Illinois Council*, 529 U.S. at 23. In this case, Plaintiffs have satisfied the presentment requirement and waiver of exhaustion is appropriate.

#### **1. Plaintiffs Have Satisfied the Presentment Requirement.**

Plaintiffs clearly have satisfied the presentment requirement with respect to their two-midnights claim, and indeed the Secretary never argues otherwise. *See* Def. Mem. 15-17.

The presentment requirement sets a low bar, and “the courts that have dealt with presentment have interpreted the requirement ‘liberally.’ ” *Linquist v. Bowen*, 813 F.2d 844, 887 (8th Cir. 1987) (citation omitted). The requirement is satisfied where a claimant presents his or her claim to the Medicare administrative contractors “who make initial payment determinations[.]” *Tataranowicz* at 272; *see also Ryan v. Bentsen*, 12 F.3d 245, 247 n.3 (D.C. Cir. 1993) (presentment satisfied where plaintiff requested reconsideration of decision to terminate his benefits). But not even that much is required. The Supreme Court has held that a plaintiff satisfies presentment where he answers an agency questionnaire and sends a letter to the agency in response to a tentative determination that his disability had ceased. *See Eldridge*, 424 U.S. at 329; *Heckler v. Lopez*, 464 U.S. 879, 882 (1983). And this Court has held that plaintiffs satisfy presentment where they, or an association representing their legal interests, send a letter to the agency setting forth their legal contentions. *Action Alliance of Senior Citizens v. Johnson*, 607 F. Supp. 2d 33, 37-39 (D.D.C. 2009) (“*Action Alliance I*”) *aff’d sub nom. Action Alliance of Senior Citizens v. Sebelius*, 607 F.3d 860 (D.C. Cir. 2010) (“*Action Alliance II*”).

Plaintiffs have satisfied the presentment requirement many times over. Each of the four Plaintiff hospitals has appealed claims denied for failure to comply with the two-midnights rule. And each specifically challenged the legality of the two-midnights rule in its requests for redetermination. Banner Decl. ¶¶ 10-11; Einstein Decl. ¶¶ 11-12, 15-16; Mount Sinai Decl. ¶¶ 9-10.<sup>11</sup> Banner Health and Einstein also requested reconsideration by the Qualified Independent Contractor (“QIC”); again arguing that the two-midnights rule is arbitrary and capricious.

---

<sup>11</sup> Plaintiffs have attached exhibits with additional facts establishing this Court’s jurisdiction. A court may look beyond the complaint to establish jurisdiction in response to a Rule 12(b)(1) motion. *See supra* at 10. If, however, the Court concludes that these facts must be in the pleadings, Plaintiffs respectfully request leave to amend the Complaint. *See Fed. R. Civ. P. 15* (court “should freely give leave [to amend] when justice so requires.”).

Banner Decl. ¶ 14; Einstein Decl. ¶ 18. They asked the QIC to declare the rule invalid. Banner Decl. ¶ 15; Einstein Decl. ¶ 19.

The Plaintiff hospitals thus have “present[ed] a claim for benefits to . . . the fiscal intermediaries who make initial payment determinations on [the Secretary’s] behalf.” *Tataranowicz*, 959 F.2d at 272. No more is needed. But Plaintiffs have done more: On April 7, 2014, the AHA sent the Secretary a letter presenting its claims on behalf of its members, including the Plaintiff hospitals. *See* Compl. ¶ 80. The letter objected to all three policies challenged in this litigation as unlawful under the APA and the Medicare Act and requested that the Secretary abandon these rules. *Id.*; Ex. A (Letter from Richard Umaddenstock to Secretary Sebelius) (April 7, 2014). Because either the association or its members can satisfy presentment, and Plaintiffs set forth the specific bases for the relief requested in the letter—the same claims at issue in this case—the letter independently satisfies the presentment requirement. *See Action Alliance I*, 607 F. Supp. 2d at 37-39; *Action Alliance II*, 607 F.3d at 862 n.1.

2. Exhaustion of Administrative Remedies Would Be Futile.

That leaves only the exhaustion requirement, and this is a model case for waiver.

The exhaustion doctrine is “intensely practical[.]” and should be “guided by the policies underlying” it. *Bowen v. City of New York*, 476 U.S. 467, 484 (1986). Where the purposes of exhaustion would not be served, courts have discretion to excuse the requirement. *See id.* (finding that purposes of exhaustion would not be served by requiring it); *Hall v. Sebelius*, 689 F. Supp. 2d 10, 18, 24 (D.D.C. 2009) (excusing exhaustion on futility grounds).

The leading D.C. Circuit case on Medicare exhaustion is *Tataranowicz*. The court there explained that courts can and do “excuse[ ] non-compliance” with the exhaustion requirement even “where the Secretary staunchly demands that the claim be dismissed for want of exhaustion.” 959 F.2d at 274 (collecting cases). And it explained that while Supreme Court

cases have excused exhaustion under several different rationales, the courts are empowered to do so “pure[ly]” on the ground that further administrative proceedings would be futile. *Id.*

The *Tataranowicz* court then examined the facts before it: The plaintiffs raised only a systemwide issue of law that, if decided in their favor, would render them eligible for benefits. *Id.* The Secretary had taken a position adverse to the plaintiffs on the issue in dispute, and he “d[id] not argue that the ALJs are free to disregard his ruling”; the Secretary accordingly had given “no reason to believe that the agency machinery might accede to plaintiffs’ claims.” *Id.* And given that plaintiffs raised a legal issue, it was “hard to see how any factual disputes might stand in the way” of the relief they requested. *Id.* On those facts, the Court of Appeals concluded, “it seems wholly formalistic not to regard further appeals as completely futile.” *Id.* Put another way, requiring exhaustion would be pointless because judicial resolution of the claim “(1) will not interfere with the agency’s efficient functioning; (2) will not thwart any effort at self-correction; (3) will not deny the court or parties the benefit of the agency’s experience or expertise; and (4) will not curtail development of a record useful for judicial review.” *Id.* at 275.

*Tataranowicz* points the way to the proper outcome. Here, as in *Tataranowicz*, Plaintiffs challenge generally applicable legal rules, factual development would not aid the Court, and the Secretary has made clear that her administrative machinery will not accede to Plaintiffs’ claims. Moreover, futility is particularly apparent here because, as a result of an extraordinary backlog of appeals pending before the Secretary’s ALJs, Plaintiffs would be forced to wait some *five years* to obtain a ruling that could never provide the relief they seek. We address these points in turn.

***Challenge to a systemwide legal rule.*** The Plaintiff hospitals are not challenging individual benefit determinations based on facts unique to each claim. If they were, the Secretary’s assertion that an administrative record must be developed to allow assessment of

Plaintiffs' claims, *see* Def. Mem. 19, might have some merit. Instead, Plaintiffs are challenging a systemwide, generally applicable interpretation of the Medicare statute: the Secretary's re-defining of the word "inpatient." *See supra* at 1. Further factual development in administrative proceedings would have no bearing on these legal claims. Waiver, in other words, "will not curtail development of a record useful for judicial review." *Tataranowicz*, 959 F.2d at 275.

Faced with similar challenges to a systemwide "policy, pattern, and practice," this Court has held time and again that the exhaustion requirement should be excused because factual development is unnecessary and "agency expertise would provide no benefit to the judicial solution of th[e] case." *DL v. District of Columbia*, 450 F. Supp. 2d 11, 18 (D.D.C. 2006); *Hall*, 689 F. Supp. at 24 (exhaustion futile because plaintiffs challenged generally applicable policy and "no facts unique to any of their claims" would change outcome in a given case); *Tataranowicz v. Sullivan*, 753 F. Supp. 978, 987 (D.D.C. 1990), *rev'd on other grounds*, 959 F.2d 268 (D.C. Cir. 1992) (exhaustion may be excused where claimant asserts "systemwide" policy that "does not depend on the particular facts of the claimant's case"). So too here.

The Secretary protests that the two-midnights rule sets forth only a *presumption*, not a *per se* rule, and thus factual development of Plaintiffs' administrative appeals is required. Def. Mem. 18. After all, the Secretary says, "shorter stays may still be reimbursed under Part A, depending on the circumstances—for example, when the physician's expectation that the patient would need a longer hospital stay was reasonable though ultimately incorrect[.]" *Id.* Thus, she says, the hospitals' "pending administrative appeals may result in payment of their initially denied claims." *Id.* But that argument misses the point entirely: Plaintiffs challenge the very notion that an *expectation* of a two-midnight stay should be required to make someone an "inpatient." Thus they argue in their administrative appeals that the admitting physician should

not have *had* to expect a stay beyond twenty-four hours, because that is not what “inpatient” means. That is a purely legal challenge, and no factual development is required.<sup>12</sup>

***Agency machinery will not accede.*** Waiver of exhaustion likewise is appropriate because the Secretary has “evidenced a strong stand” on the two-midnights rule and has “shown an unwillingness to reconsider[.]” *Randolph–Sheppard Vendors of Am. v. Weinberger*, 795 F.2d 90, 106 (D.C.Cir.1986). The Secretary definitively construed the word “inpatient” in a binding, legislative rule. *See* 78 Fed. Reg. at 50,908, 50,949, 50,965. And she already has refused to reconsider: After publication of the proposed rule, many commenters expressed concerns about serious flaws in the policy, *see, e.g., id.* at 50,945, and the Secretary summarily dismissed those objections, *see id.* at 50,946. Moreover, after the Secretary adopted the Final Rule, the AHA sent a letter to CMS requesting delayed enforcement of the two-midnights and physician-order rules, *see* Letter from Linda Fishman to Jonathan Blum (Sept. 18, 2013), *available at* <http://www.aha.org/advocacy-issues/letter/2013/130918-cl-2midnight.pdf>, and the agency refused to grant this request. *See* Letter from Marilyn Tavenner to Richard Umbdenstock (Sept. 26, 2013), on file with author. To the contrary, the Secretary has instructed her contractors to review samples of each hospital’s inpatient claims spanning less than two midnights and deny all claims that do not comply with the rule. CMS, *Selecting Hospital Claims for Patient Status Reviews*, at 1-2 (Feb. 24, 2014).<sup>13</sup>

---

<sup>12</sup> The Secretary also points out two other exceptions to the rule: a limited list of “inpatient only” services, 78 Fed. Reg. at 50,947, and some nebulous “rare and unusual” circumstances in which shorter stays might be treated as inpatient stays, *id.* at 50,946. But these exceptions are just that—narrow exceptions to a per se rule. And Plaintiffs do not rely on them in their agency appeals; they instead argue that the two-midnights rule itself is invalid as a matter of law.

<sup>13</sup> *Available at* <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/Downloads/SelectingHospitalClaimsForAdmissionsForPosting02242014.pdf>

Nor could the administrative process even grant Plaintiffs the relief that they seek. Despite the Secretary's attempts at misdirection, *see* Def. Mem. 17-19, Plaintiffs are not interested in just obtaining payment for individual claims. Plaintiffs instead seek a declaration that the two-midnights rule is unlawful. Compl. ¶ A. But administrative appeal adjudicators are required to comply with the two-midnights rule; they are not empowered to invalidate it. *See* 42 C.F.R. § 405.968(b)(1) (“[A]pplicable . . . regulations are binding on the QIC.”); 42 C.F.R. § 405.1063 (“All . . . regulations pertaining to the Medicare and Medicaid programs . . . are binding on ALJs and the [DAB].”). Only this Court can do that.

In circumstances like these, requiring exhaustion is “clearly useless[.]” *Randolph-Sheppard*, 795 F.2d at 106; *accord Califano v. Goldfarb*, 430 U.S. 199, 201 n.3 (1977); *Etelson v. Office of Pers. Mgmt.*, 684 F.2d 918, 925 (D.C. Cir. 1982). The Secretary “has made known that [her] general views are contrary to those of the complainant,” *Etelson*, 684 F.2d at 925, and her adjudicators are not “free to disregard [her] ruling,” *Tataranowicz*, 959 F.2d at 274.

**ALJ delay.** As a practical matter, it would be particularly unjust to require exhaustion here because not only are Plaintiffs definitively precluded from obtaining the relief they seek, but it likely would take them a half-decade to obtain these useless rulings. That is so because of a massive logjam at the ALJ level of review. The HHS Office of Medicare Hearings and Appeals (“OMHA”) recently announced a moratorium on assignment of provider appeals to ALJs for at least two years, and possibly longer. And that is just the time required to get the wheels turning; an ALJ hearing likely would not occur for many months after that, with a decision date even later. *See* Office of Medicare Hearings & Appeals, Adjudication Timeframes, [http://www.hhs.gov/omha/important\\_notice\\_regarding\\_adjudication\\_timeframes.html](http://www.hhs.gov/omha/important_notice_regarding_adjudication_timeframes.html).

As of July 1, 2014, some 800,000 appeals were pending at the ALJ level—many

involving RAC denials of Part A inpatient stays. Statement of N. Griswold before U.S. House Committee on Oversight and Government Reform, Subcommittee on Energy Policy, Health Care & Entitlements (July 10, 2014), <http://oversight.house.gov/wp-content/uploads/2014/07/CMS-Griswold-OMHA-Final.pdf>; OMHA Medicare Appellant Forum Presentation 108 (Feb. 12, 2014), [http://www.hhs.gov/omha/omha\\_medicare\\_appellant\\_forum\\_presentations.pdf](http://www.hhs.gov/omha/omha_medicare_appellant_forum_presentations.pdf) (RAC appeals account for 36 percent of the total appeals volume for FY 2013). Plaintiffs should not have to spend years administratively challenging an unlawful policy that cannot be addressed by the administrative process anyhow. They deserve their day in court now, not in 2020.

**B. This Court Has Jurisdiction Over Plaintiffs’ Physician-Order Challenge.**

The Secretary levels additional fire at Plaintiffs’ physician-order challenge: not only does she complain about exhaustion, but she asserts that Plaintiffs have not presented their claims, that they lack standing, and that their challenge is not ripe. Each argument lacks merit.

1. Plaintiffs Have Presented Their Claims And Exhaustion Should Be Waived.

The presentment and exhaustion analyses are near-identical to those already discussed, so we address them only briefly. The Secretary asserts that the Plaintiff hospitals have not even presented physician-order claims to the agency, but that is incorrect: Banner Health already has appealed one of these claim denials for failure to comply with the physician-order rule. Banner Decl. ¶¶ 16-17. Moreover, the AHA also has submitted a letter to the Secretary presenting its physician-order claims on behalf of its members, including the Plaintiff hospitals, *see* Compl. ¶ 80, and that letter independently satisfies the presentment requirement. *See Action Alliance I*, 607 F. Supp. 2d at 37-39; *Action Alliance II*, 607 F.3d at 862 n.1.

Waiver of exhaustion also is appropriate for the reasons already discussed with respect to the two-midnights rule. First, the Plaintiff hospitals are challenging a pure legal issue of general

applicability; their challenge is in no way dependent on the particular facts of a claimant's case. *See DL*, 450 F. Supp. 2d at 17-18; *accord Hall*, 689 F. Supp. at 24; *Tataranowicz*, 753 F. Supp. at 987. Second, the Secretary has adopted a firm position on the current physician-order rule, adopting it as a regulation, and administrative appeal adjudicators are not empowered to invalidate it. *See, e.g., Randolph-Sheppard*, 795 F.2d at 106.

Once again, the Secretary argues that the physician-order rule is not a “per se” rule—this time because Medicare contractors have “discretion to determine” whether the requirement is “constructively satisfie[d].” Def. Mem. 22. Thus, the government says, factual development is important. But again, this argument does not hold water. Even assuming a contractor does have such discretion (an assumption not supported by the regulation's text), that is irrelevant to Plaintiffs' contention in this case: that as a matter of law, no physician order can be required at all as a condition of payment. That is a legal challenge on which any record developed in administrative appeals has no bearing. Exhaustion should be waived.

## 2. Plaintiffs Have Standing.

The Secretary's standing argument is similarly meritless. Plaintiffs have standing for a simple reason: Medicare has denied their claims for reimbursement pursuant to the physician-order rule, *see supra* at 4, and if this Court invalidates the physician-order rule, those claims will be paid. Plaintiffs thus have suffered an injury-in-fact—loss of money—that is “concrete and particularized,” and a favorable decision from this Court would redress it. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992); *see Urban Health Care Coal. v. Sebelius*, 853 F. Supp. 2d 101, 105 (D.D.C. 2012) (hospital allegations that a Medicare policy reduced its reimbursement constitutes a “concrete, actual harm to the Hospitals' financial interests and is sufficient to satisfy the requirement of injury in fact”).

The Secretary nonetheless says Plaintiffs lack standing because she already required physician orders documenting inpatient admission as a condition of hospitals' participation in the Medicare program. Given that fact, the Secretary says, "the regulation imposes no new legal obligation" on Plaintiffs. Def. Mem. 20. But that argument disingenuously conflates two separate requirements. To be sure, Medicare imposes various "conditions of participation," on hospitals, *see generally* 42 C.F.R. § 482.1 & Part 482; included among them are requirements that licensed practitioners make recommendations for inpatient admissions, 42 C.F.R. § 482.12(c)(2), and patient medical records include "orders" for care, *id.* § 482.24(c)(2); and hospitals work hard to comply. But there is no consequence under that regulation for a hospital that makes a one-off technical error in documenting a particular patient's physician order: Hospital compliance with the conditions of participation is assessed through surveys, 42 C.F.R. § 482.1; *id.* §§ 488.3, .20, .26, and if a hospital is deficient with respect to a standard, it typically must enter into a corrective action plan and achieve compliance within a "reasonable" period of time, 42 C.F.R. § 488.28. Thus isolated instances of non-compliance have never affected whether the hospital can collect Medicare reimbursement for a patient's inpatient stay.

Until now, that is. By making the physician order a condition of *payment*, the Secretary has told her contractors to refuse to reimburse a hospital when it makes a one-off technical foot-fault in documenting a particular patient's admission. *See* 42 C.F.R. § 424.13. And that is exactly what has happened to Plaintiffs here: They have been denied payment under the new physician-order rule, whereas they would have had no financial consequences under the pre-existing conditions of participation. *See supra* at 4. Put another way, Plaintiffs have a financial injury that they would not have suffered absent the new rule. Given that fact, it is absurd to suggest that the conditions of participation somehow strip Plaintiffs of standing.

3. Plaintiffs' Physician-Order Challenge Is Ripe.

Plaintiffs' challenge to the physician-order requirement is likewise ripe.

The Secretary devotes more than five pages to the assertion that her recently published Notice of Proposed Rulemaking, suggesting a different legal basis for the physician-order requirement in future years, renders Plaintiffs' claim unripe because "the outcome of the pending rulemaking may afford Plaintiffs relief." Def. Mem. 23-28. But the proposed rulemaking is nothing more than a red herring. That is so because the proposed rule—whenever it is finalized, and whatever it may eventually say—has no bearing whatsoever on Plaintiffs' claims for Part A reimbursement that *already have been denied* under the current rule.

The current physician-order rule is final: It applies to all Medicare discharges that occur on or after October 1, 2013. Plaintiffs must comply with its requirements and have been denied Medicare payment for inpatient stays where they did not. And Plaintiffs argue in this case that those payments were improperly denied because the physician-order rule is unlawful. The only way to resolve that claim is to determine whether the current physician-order rule, on which the reimbursement denials rest, is in fact unlawful. What the Medicare regulations may provide in the future cannot obviate the need to decide the issue here presented: whether the reimbursement denials of which Plaintiffs complain amounted to unlawful agency action.

Indeed, the proposed rule, if adopted, would apply to claims for reimbursement *only on or after January 1, 2015*. See 79 Fed. Reg. 90,416 (July 14, 2014). The Secretary does not suggest that the rule would apply retroactively, *see id.*, and thus even if the rule were finalized as proposed, it would not remedy the lost reimbursement Plaintiffs have experienced and will continue to experience under the existing rule. The Secretary's focus on ripeness is inexplicable.

The Secretary nevertheless forges ahead, trotting out cases in which the courts found disputes unripe amid continued agency rulemaking. Def. Mem. 25-27. The government

apparently fails to recognize the fundamental difference between those cases and this one: In each of its cited cases, the ongoing agency rulemaking *had the potential to obviate the plaintiffs' complaint*. See, e.g., *Am. Petroleum Inst. v. E.P.A.*, 683 F.3d 382, 388 (D.C. Cir. 2012) (challenge to agency rule unripe where litigant had not been injured by the “tentative” rule in question and the agency was considering whether to eliminate it altogether); *Lake Pilots Ass’n, Inc. v. U.S. Coast Guard*, 257 F. Supp. 2d 148, 161 (D.D.C. 2003) (challenge unripe where agency “admitted its error” and “reinstated the prior rates that were in effect prior to the adoption of the [challenged] 2001 Final Rule, pending resolution of the issue”). Not so here: No matter what the Secretary does going forward, Plaintiffs still will have lost reimbursement under the *current* rule. That rule’s validity thus must be addressed; there is no other way to resolve Plaintiffs’ claims. Delaying review will not save the Court any effort because this is not a case that can “go[] away without the need for judicial review.” *Am. Petroleum*, 683 F.3d at 388.

**C. This Court Has Jurisdiction Over The One-Year Time Limit Challenge.**

The government argues, finally, that this Court lacks jurisdiction over the one-year time limit challenge due to failures of presentment, exhaustion, and standing, among other things. Again, its arguments should be rejected.

1. Plaintiffs Have Presented Their Claims And Exhaustion Should Be Waived.

As explained *supra* at 30, Plaintiffs satisfied the presentment requirement of § 405(h) by sending a letter to the Secretary on April 7, 2014. See, e.g., *Action Alliance I*, 607 F. Supp. 2d at 37-39; *Action Alliance II*, 607 F.3d at 862 n.1. And, as with the two-midnights and physician-order challenges, Plaintiffs are challenging a pure legal issue of general applicability that is not dependent on individualized facts. See *DL*, 450 F. Supp. 2d at 17-18; *Hall*, 689 F. Supp. at 24; *Tataranowicz*, 753 F. Supp. at 987. In addition, the Secretary has staked out a final position on

the one-year time limit, and administrative appeal adjudicators are not empowered to invalidate it. *See Randolph-Sheppard*, 795 F.2d at 106; *Califano*, 430 U.S. at 201 n.3; *Etelson*, 684 F.2d at 925. The exhaustion requirement accordingly should be waived.

2. Plaintiffs Have Standing.

Plaintiffs likewise have standing. In pre-enforcement challenges one “does not have to await the consummation of threatened injury to obtain preventative relief.” *Babbitt v. United Farm Workers Nat’l Union*, 442 U.S. 289, 298 (1979). Rather, “a realistic danger of sustaining a direct injury as a result of the statute’s operation or enforcement” is enough. *Id.*

There is more than a “realistic danger” of injury here. As an initial matter, the Plaintiff hospitals are the direct objects of the rule, and they are the entities that will be injured by its enforcement. As the Supreme Court explained in *Lujan*: “[w]hen the suit is one challenging the legality of government action or inaction, . . . [if] the plaintiff is himself an object of the action (or forgone action) at issue. . . . [T]here is ordinarily little question that the action or inaction has caused him injury, and that a judgment preventing or requiring the action will redress it.” *Lujan*, 504 U.S. at 561–62 (emphasis added); *see also Fund for Animals, Inc. v. Norton*, 322 F.3d 728, 733–34 (D.C. Cir. 2003) (observing that a party’s standing to seek review of administrative action is typically “self-evident” when the party is the object of the action). Going forward, Plaintiffs will suffer great economic loss because the application of the one-year time limit means that hospitals almost *never* will be paid for denied Part A claims. Compl. ¶ 105.

But Plaintiffs also will suffer even more immediate injury. In the coming months, the Plaintiff hospitals will be required either to withdraw their pending Part A administrative appeals so they can meet the one-year deadline to rebill under Part B, or continue to pursue their Part A appeals but lose the ability to rebill under Part B. Banner Decl. ¶ 23; Einstein Decl. ¶ 25; Mount Sinai Decl. ¶ 16. The hospitals, in other words, will face a Hobson’s choice: relinquish an

appeal they think meritorious or forgo the Part B reimbursement to which they are entitled. That amounts to an injury in fact. *C.f. Hotze v. Sebelius*, 2014 WL 109407, at \*4 (S.D. Tex. Jan. 10, 2014) (finding standing where employer will be forced to choose between incurring penalties or switching to more expensive and less desirable health insurance coverage). And the temporal definiteness of the injury—it is coming, unavoidably, in just a few months—means the “imminence” requirement is satisfied. *See, e.g., Mead v. Holder*, 766 F. Supp. 2d 16, 25 (D.D.C. 2011) (finding imminence where plaintiffs “have given a definite point in time by which their injury will occur . . .”), *aff’d sub nom. Seven-Sky v. Holder*, 661 F.3d 1 (D.C. Cir. 2011) *abrogated by Nat’l Fed’n of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566 (2012).

Plaintiffs’ injuries thus are certain, and that means they have more than cleared the bar, for certainty is not required. In *Mead v. Holder*, this Court noted that “[a]lthough it cannot be said with absolute certainty that Plaintiffs will qualify as individuals subject to the minimum essential coverage requirement in 2014, such a conclusion is not required.” 766 F. Supp. 2d at 25. “All that is required is that Plaintiffs allege a substantial probability . . .” *Id.* The Secretary cannot seriously dispute that a “substantial probability” of harm also exists here.

As the Plaintiff hospitals are the objects of the government action, there is “little question . . . that a judgment preventing or requiring the action will redress it.” *Lujan*, 504 U.S. at 561-62. Indeed, if this Court finds the one-year time limit unlawful, Plaintiffs will not be denied the Part B reimbursement to which they are legally entitled, nor will Plaintiffs be forced to choose between exercising their right to appeal and claiming Part B reimbursement. They accordingly satisfy the redressability prong as well.

3. The Secretary’s Characterization Of Plaintiffs’ One-Year Time Limit Challenge Should Be Rejected.

Hoping to persuade this Court not to exercise jurisdiction, the Secretary characterizes her

Part B rebilling policy as a “claims processing decision” either to deny (i) a request to reopen a particular Part A claim or (ii) a request for an extension of the time limit to rebill under Part B for that claim. Def. Mem. 31-32. The Secretary says such decisions are not “final decisions . . . made after a hearing” under § 405(g) and thus that Plaintiffs cannot obtain judicial review—at all, ever—of the Secretary’s new rule of general applicability. *Id.* at 32. The argument fails. The Secretary is well-aware that Plaintiffs are not challenging a “claims processing decision.”

a. Plaintiffs have made clear that they are challenging the validity of a generally-applicable rule: namely, the Secretary’s policy of requiring hospitals to rebill under Part B after a Part A denial and applying the one-year time limit to those rebilled claims. *See* Compl. ¶¶ 51-52. As explained above, nothing prevents the Secretary from instructing contractors to adjust the reviewed Part A claims, by offsetting the amount of Part B payment against the Part A “overpayment.”<sup>14</sup> *See supra* at 18. Likewise, nothing prevents the Secretary from creating an exception to the one-year time limit, as she has done in analogous circumstances. *See supra* at 20. Plaintiffs thus argue that the Secretary’s chosen policy—a policy enshrined through notice-and-comment rulemaking, and applicable across the board—is arbitrary and capricious. That is precisely the sort of legal issue over which this Court has jurisdiction. *See supra* at 39.

The Secretary’s contention that Plaintiffs’ challenge is unreviewable rests on viewing that challenge as a writ-large request for “reopening” claims denied under Part A. Presumably, the

---

<sup>14</sup> The Secretary’s suggestion that Plaintiffs’ requested “adjustment” or “supplement” to the existing Part A claims is possible only if an unfavorable payment determination is first reopened, Def. Mem. 32 n.12, misses the point: the claims that are subject to post-payment review have already been reopened by the RAC and remain open until the revised determination is issued by the Medicare Administrative Contractor. *See* 42 C.F.R. § 405.982(a); RAC Statement of Work at 14; MCPM Ch. 34 § 10.9. As the DAB and ALJs recognized, nothing would prevent the contractor from adjusting the payment amount. *See, e.g., In re: Hendrick Med. Ctr.*, 2012 WL 2324891, at 5-6 (invoking concepts of adjustment billing and directing contractor pay the hospital bill under Part B ); *UMDNJ-Univ. Hosp.*, 2005 WL 6290383 (same).

Secretary hopes that if she puts Plaintiffs' challenge in the "reopening" box, she can rely on the Ninth Circuit decision in *Palomar Medical Center v. Sebelius*, where the court held that whether a RAC had "good cause" to reopen a hospital's claims for services was not subject to further administrative or judicial review under § 405(g). 693 F.3d 1151, 1166-67 (9th Cir. 2012).

But at the same time, the Secretary has claimed that rebilling under Medicare Part B after a Part A denial requires a separate "new" claim because "the nature of the original claim is fundamentally changed from a Part A claim to a Part B claim." *See* 78 Fed. Reg. at 50,922, 50,924. If the Court takes the Secretary at her word, then "reopening" the "initial determination" is wholly irrelevant. As the Secretary herself has explained, a reopening is an action taken to "change a binding determination or decision that resulted in either an overpayment or an underpayment," which may be taken by "a contractor *to revise the initial determination or redetermination.*" 42 C. F. R. § 405.980(a) (emphasis added). A subsequent request for Part B payment, if it is truly "separate" as the Secretary suggests, cannot be a request to reopen that revised Part A initial determination. The Secretary cannot have it both ways.

In the alternative, the Secretary attempts to re-characterize Plaintiffs' challenge as a request for an extension of the one-year time limit—again writ-large—that would otherwise apply to their rebilled Part B claims. Def. Mem. 35-36. The Secretary asserts that under that formulation, too, Plaintiffs' challenge is unreviewable because it is not a "final decision . . . after a hearing." She argues that the "reasoning of *Palomar* also compels the conclusion that the Court lacks jurisdiction to review the claims processing decision whether to extend the one-year statutory limitation period for Medicare payment claims" because Medicare regulations provide that "determinations that a provider or supplier failed to submit a claim timely" are not "initial determinations." Def. Mem. 35. But that argument also misses the mark. Unlike Plaintiffs'

challenge, *Palomar* involved a dispute over the reopening of specific claims for services—i.e., “claims processing decisions.” *See Palomar*, 693 F.3d at 1157-58. Moreover, *Palomar* applies only to reopenings; it hardly “compels” the conclusion that there is no judicial review of the Secretary’s blanket policy refusing to extend the time for filing Part B claims like those here. The Secretary cannot overcome the “strong presumption” favoring judicial review. *Urological Interests*, 668 F.3d at 708.

b. Even if the Court were to accept the Secretary’s re-formulation of Plaintiffs’ complaint—which it should not—as either a request for reopening or a request for an extension of the one-year time limit *and* agree that such requests are not “final decisions” for purposes of § 405(h), the Court still would have jurisdiction under 28 U.S.C. § 1331.<sup>15</sup>

The Supreme Court has explained that “§ 1395ii does not apply § 405(h) where application of § 405(h) would not simply channel review through the agency, but would mean no review at all.” *Illinois Council*, 529 U.S. at 19. Put differently, Plaintiffs are not subject to the presentment or exhaustion requirements where they would be the “practical equivalent of a total denial of judicial review[.]” *Id.* (quoting *McNary v. Haitian Refugee Ctr., Inc.*, 498 U.S. 479, 497 (1991)); *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 680 (1986) (rejecting government’s assumption that Congress “intended no review at all of substantial statutory and constitutional challenges to the Secretary’s administration of Part B of the Medicare program”); *Urological Interests*, 668 F.3d at 709. As the D.C. Circuit has explained, “the *Illinois Council* inquiry is fundamentally a practical one. The exception applies not only when administrative

---

<sup>15</sup> The Court need not reach this argument because it has jurisdiction under the Medicare Act, as explained above. However, to the extent the Court does reach this argument, Plaintiffs request leave to amend their Complaint to add a single sentence asserting that the Court has jurisdiction pursuant to Section 1331. *See* Fed. R. Civ. P 15.

regulations foreclose judicial review, but also when roadblocks practically cut off any avenue to federal court.” *Id.* at 712 (internal quotations omitted).

This exception makes good sense. After all, courts “begin with the strong presumption that Congress intends judicial review of administrative action” and that “judicial review of a final agency action by an aggrieved person will not be cut off unless there is persuasive reason to believe that such was the purpose of Congress[.]” *Id.* at 708 (quoting *Mich. Acad.*, 476 U.S. at 670). “To overcome this presumption, the government bears a heavy burden.” *Id.* at 709.

If the Court were to accept the government’s characterization of Plaintiffs’ challenge as a request for reopening or a request for an extension of the one year time-limit, applying the channeling requirements of § 405(h) would foreclose judicial review. According to the Secretary, Plaintiffs could never obtain a “final decision . . . after a hearing” because Medicare regulations provide that a contractor’s decision denying a request for reopening or rejecting a claim as untimely is not an “initial determination” and therefore cannot be litigated through the administrative appeals process. 42 C.F.R. § 405.926(l), (n). But if that’s so, then applying § 405(h) would mean “no review at all.” *Illinois Council*, 529 U.S. at 19. And in those circumstances, the D.C. Circuit has concluded that there is federal question jurisdiction under 28 U.S.C. § 1331 instead. *See Urological Interests*, 668 F.3d at 714.

### CONCLUSION

For all of the foregoing reasons, Plaintiffs respectfully request that the Court deny Defendant’s motion to dismiss and grant Plaintiffs’ motion for summary judgment.

Dated: August 4, 2014

Respectfully Submitted,

/s/ Dominic F. Perella  
Sheree R. Kanner (D.C. Bar No. 366926)

Dominic F. Perella\* (D.C. Bar No. 976381)  
Margia K. Corner (D.C. Bar No. 1005246)  
Jennifer D. Brechbill (D.C. Bar No. 1011454)  
HOGAN LOVELLS US LLP  
555 Thirteenth Street, N.W.  
Washington, D.C. 20004  
(202) 637-5600

*\* Counsel of Record*

Melinda Reid Hatton (D.C. Bar No. 419421)  
Lawrence Hughes (D.C. Bar. No. 460627)  
AMERICAN HOSPITAL ASSOCIATION  
325 Seventh Street, NW  
Washington, DC 20001  
(202) 638-1100

*Attorneys for Plaintiffs*

**REQUEST FOR ORAL HEARING**

Plaintiffs respectfully request an oral hearing on their motion.

/s/ Dominic F. Perella  
Dominic F. Perella (D.C. Bar No. 976381)