UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*, Plaintiffs, v. KATHLEEN SEBELIUS, in her official capacity as Secretary of Health and Human Services, Defendant.	Case No. 1:12-cv-1770-CKK

PLAINTIFFS' OPPOSITION TO DEFENDANT'S MOTION TO DISMISS

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INTRODUCTION

In her motion to dismiss, the Secretary of Health and Human Services derisively paints the plaintiff hospitals as tardy litigants looking for a second bite at the apple. According to the Secretary, her Recovery Audit Contractors (RACs) "caught" the hospitals making billing errors; the hospitals then "slept on their rights" when they could have appealed the RAC decisions; and the hospitals are now inappropriately "pursuing their claims in every available forum, simultaneously." Defendant's Memorandum in Support of Mot. Dismiss ("Def. Mem.") at 1, 12. If the hospitals would only wait for the administrative process to run its course, rather than "jump[ ] the gun," the Secretary soothingly suggests, her policies eventually would be reviewed. *Id.* at 20. She thus urges this Court to dismiss the Complaint.

The Court should recognize this narrative for what it is: the latest example of "legal gamesmanship" by the Secretary aimed at furthering a long-running "administrative shell game." *Allina Health Servs.* v. *Sebelius*, 904 F. Supp. 2d 75, 78 n.2, 91 (D.D.C. 2012). Here is the real story of this case: Having abandoned one rationale for refusing to pay hospitals hundreds of millions of dollars to which they are legally entitled, the Secretary has of late embraced a second one, and she now asks this Court to completely insulate her latest justification from judicial review. The Court should decline the invitation.

This case began with plaintiffs' challenge to CMS's "Payment Denial Policy." Using RACs compensated in proportion to the money they recover, CMS claws back Medicare Part A payments from hospitals on the ground that particular patients should not have been admitted to the hospital to receive inpatient care, but instead should have received the care on an outpatient basis. In such cases, where CMS's only objection is to the *setting* in which care was provided, CMS is required by law to pay the hospitals under Medicare Part B, which provides coverage for

outpatient services. For years, however, CMS categorically refused to pay. That Payment Denial Policy meant hospitals received no reimbursement for hundreds of millions of dollars' worth of necessary care—surgeries, drugs, and the like—they provided to Medicare beneficiaries.

The plaintiff hospitals in this case, joined by the American Hospital Association (AHA), filed suit last year and asked this Court to invalidate that policy as arbitrary, capricious, and contrary to law. Rather than defend its policy, CMS folded its tent: Two days before it was to make its first substantive filing in this litigation, it issued a ruling (Ruling 1455-R) and notice of proposed rulemaking that withdrew the Payment Denial Policy, effective immediately, and concluded that "*under section 1832 of the [Social Security] Act, Medicare should pay*" for the very services it had long refused to pay for under the policy. *Medicare Program; Part B Inpatient Billing in Hospitals*, 78 Fed. Reg. 16,632, 16,636 (Mar. 18, 2013) (emphasis added). CMS, in other words, confessed error. It said it should have been paying hospitals under Part B all along.

So far, so good. But CMS made its ruling applicable *only* to RAC denials that are still live on appeal or for which the time to appeal has not run—meaning that hospitals still cannot obtain the Part B payment to which CMS itself says they are entitled in the vast majority of cases where they suffered a RAC clawback. The agency also announced that even in cases where the hospital can rebill, CMS will not pay for services that it deems to require an "outpatient" status.

On their face, these new CMS policies doom any attempt by the plaintiffs to obtain the Part B payments they are owed in most cases, including those set forth in the Second Amended Complaint (Complaint). Because CMS's effort to give with one hand and take back with the other is arbitrary and capricious (among other flaws), the plaintiffs amended their Complaint to challenge the new policies. Before doing so, however, they did what the Medicare Act requires: They presented their requests for Part B payment to CMS in the first instance. Specifically, they

used every available administrative mechanism to submit adjusted or supplemented bills to CMS's contractors, seeking reimbursement under Part B for services that they provided to beneficiaries but that are excluded from payment under the new CMS policies. *See, e.g.*, Cmplt. ¶¶ 77-124.

Unsurprisingly, the Secretary now says plaintiffs' presentment of their requests for payment is not enough to confer jurisdiction on this Court. Indeed, the Secretary mocks plaintiffs' efforts to meet the presentment requirement. *See* Def. Mem. 2. Her sarcasm is unwarranted; each of her arguments for dismissal misses the mark.

First, the Secretary argues that the hospitals have not exhausted their administrative remedies. That argument fails because there is "no reason to believe that the agency machinery might accede to plaintiffs' claims." *Tataranowicz* v. *Sullivan*, 959 F.2d 268, 274 (D.C. Cir. 1992). CMS has already made perfectly clear, both in Ruling 1455-R and in its papers in this litigation, that it will not allow payment under Part B for the items and services at issue here. Moreover, plaintiffs cannot even get their foot in the door on many of their attempts to request payment under Part B; as described below, CMS's contractors are refusing to pay some of plaintiffs' revised bills and rejecting others out of hand. In such circumstances, it is "wholly formalistic not to regard further appeals as completely futile," and exhaustion is excused. *Id.*

Second, the Secretary says this dispute is not ripe because CMS's rules could change as a result of its pending rulemaking. That too is wrong. It is black-letter law that the Secretary does not have the power to promulgate regulations that operate retroactively absent an express authorization from Congress. As a consequence, the Secretary's proposed rebilling rule—whenever it is finalized—cannot have any effect on the Secretary's obligation to pay plaintiffs' claims, which have already been presented for payment under Part B. This Court will have to render judgment regardless, and there is no reason for it to stay its hand.

Third, the Secretary says this Court lacks jurisdiction because what the plaintiffs seek is really to "reopen" their Part A claims, and a contractor's decision to deny reopening is subject to no review. The argument fails twice over. This case challenges a nationally applicable CMS policy; it is not about whether particular hospital bills constitute attempts to "reopen." And in any event, even if this case *did* turn on the administrative category in which particular bills belong, the Secretary is wrong to say the bills here go in the "reopening" box. Plaintiffs not have not sought to reopen, but to adjust existing claims with new information. This "adjustment bill" process has long been available as a distinct CMS billing mechanism. And there is no question that hospitals can use it to seek Part B payment; CMS's own adjudicative bodies have ordered hospitals to do just that on many occasions *without* a reopening. The Secretary cannot ward off judicial review by arbitrarily trying to shoehorn hospitals' attempts to adjust their bills into the "reopening" box.

* * *

Make no mistake: What the Secretary seeks in this motion is to place a CMS policy of general applicability entirely beyond the reach of judicial review. After all, a hospital will have standing to challenge CMS's arbitrary limitation on Ruling 1455-R only if it suffered a RAC Part A denial and that RAC decision is no longer live on appeal. And yet on the Secretary's logic, *every* challenge brought on those facts is an attempt to "reopen" that can be rejected out of hand and placed beyond the reach of the judiciary. This Court should closely question such an approach, especially given CMS's unfortunate track record in this matter—a record of finding any excuse to deny reimbursement, "apparently because of an overriding desire to squeeze the amount of money paid to Medicare providers." *Allina*, 904 F. Supp. 2d at 84.

There is a "strong presumption that Congress intends judicial review of administrative action." *Bowen* v. *Mich. Acad. of Family Physicians*, 476 U.S. 667, 670 (1986). The Secretary has pointed to nothing that defeats that presumption here. Her motion should be denied.

BACKGROUND

Plaintiffs set forth the relevant background below, hewing largely to the allegations of the Complaint but also referring to declarations, appended as Exs. A-E, that set forth facts relevant to their efforts to present and exhaust their claims. *See Ass'n of Am. Physicians & Surgeons, Inc.* v. *Sebelius*, 901 F. Supp. 2d 19, 29 (D.D.C. 2012) (on motion to dismiss for lack of jurisdiction, "the court is not limited to the allegations of the complaint. Rather, a court may consider such materials outside the pleadings as it deems appropriate to resolve the question of whether it has jurisdiction to hear the case.") (quotation marks & citation omitted).

A. Medicare Act

Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq.*, establishes a program of health insurance for the aged and disabled, known as Medicare. Medicare is divided into four parts, A through D. Part A "covers medical services furnished by hospitals and other institutional care providers." *Northeast Hosp. Corp.* v. *Sebelius*, 657 F.3d 1, 2 (D.C. Cir. 2011); *see* 42 U.S.C. §§ 1395c to 1395i–5. "Part B is an optional supplemental insurance program that pays for medical items and services not covered by Part A, including . . . physician services, clinical laboratory tests, and durable medical equipment." *Northeast Hosp.*, 657 F.3d at 2; *see* 42 U.S.C. §§ 1395j to 1395w–4. Anyone covered by Part A may purchase Part B insurance by paying a monthly premium. *See id.* §§ 1395j, 1395o. Thus, for an individual who receives a treatment on an outpatient basis, payment to the hospital may be made under Part B, while for an individual whose risk factors support providing the same treatment on an inpatient basis, payment to the hospital may be made under Part A. To be covered by Medicare Part A or Part B, medical services must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." *Id.* § 1395y(a).

B. Medicare Payments And The Appeals Process

When a hospital or other provider treats a Medicare beneficiary, the provider typically bills CMS for the appropriate payment for the services provided. CMS, however, cannot directly process the hundreds of millions of payment claims it receives each year. It therefore contracts with Medicare administrative contractors, generally private insurance companies, to perform coverage determination and payment functions. *See Baptist Memorial Hosp.* v. *Sebelius*, 603 F.3d 57, 60 (D.C. Cir. 2010); *see also* 42 U.S.C. §§ 1395h, 1395kk–1. Providers submit claims for reimbursement to these contractors, and the contractors determine whether the services in question are covered and how much the provider is entitled to be paid. *Id.* § 1395ff(a); 42 C.F.R. § 405.920.

Those determinations are subject to administrative review. A provider can ask for redetermination of a contractor's findings. 42 C.F.R. § 405.940. If unsatisfied, the provider can seek reconsideration from a Qualified Independent Contractor (QIC), which includes an independent record review by a panel of physicians or other healthcare professionals. *Id.* § 405.960. The next step is review by an Administrative Law Judge (ALJ). *Id.* § 405.1000. The ALJ's decision, in turn, can be reviewed by the Departmental Appeals Board Medicare Appeals Council (DAB). *Id.* § 405.1130. The DAB's decision may be appealed to a federal district court. 42 U.S.C. § 405(g); 42 C.F.R. § 405.1130.

The Medicare statutes and regulations require providers to submit claims for payment within "1 calendar year after the date of service." 42 U.S.C. § 1395n(a)(1); 42 C.F.R. § 424.44. CMS is empowered to make exceptions to those time limits. 42 U.S.C. § 1395n(a) provides that "the Secretary may specify exceptions to the 1 calendar year period," and 42 C.F.R. § 424.44(b) sets forth a non-exhaustive list of circumstances in which CMS will extend the time to file. *See id.*

C. The RAC Program And CMS's Payment Denial Policy

This case arises out of the interaction between the RAC program and CMS's Payment Denial Policy. We explain them in turn.

1. The RAC Program. Traditionally, a hospital's decision to admit a patient as an inpatient has been committed to the physician's expert judgment, with hospital oversight and input from the patient. *See* Medicare Benefit Policy Manual (MBPM) Ch. 1 § 10. As CMS recognizes, the decision to admit a patient is a complex medical judgment that involves consideration of many factors, such as "the patient's medical history and current medical needs," "the types of facilities available to inpatients and to outpatients," "the relative appropriateness of treatment in each setting," "[t]he severity of the [patient's] signs and symptoms," and "[t]he medical predictability of something adverse happening to the patient." *Id.* Nonetheless, in order to receive Part A reimbursement, a hospital must establish that admitting the patient for inpatient treatment was medically necessary. 42 U.S.C. § 1395y(a).

Physicians' decisions to admit patients began coming under regular scrutiny with the advent of the RAC program. Cmplt. ¶ 34. In 2003, Congress enacted the "RAC Demonstration Project" and tasked the Secretary with implementing it. Medicare Prescription Drug, Improvement, & Modernization Act of 2003, Pub. L. No. 108–173, § 306(a), 117 Stat. 2066, 2256 (2003); *see generally* CMS, *The Medicare Recovery Audit Contractor (RAC) Program: An Evaluation of the 3-Year Demonstration* (June 2008) ("*Project Evaluation*"). Acting through CMS, the Secretary began the RAC Demonstration Project in 2005. Cmplt. ¶ 34. After the three-year RAC Demonstration Project, Congress made the program permanent in 2006. *See* Pub. L. No. 109-432, 120 Stat. 292 (2006), codified at 42 U.S.C. § 1395ddd.

RACs are private entities that contract with the federal government to audit payments made to providers and suppliers by the Medicare program. Cmplt. ¶ 35; *see St. Francis Hosp.* v. *Sebelius*, 874 F. Supp. 2d 127, 129 (E.D.N.Y. 2012). RACs typically conduct their audits by reviewing records and opining on the propriety of treatment decisions. Cmplt. ¶ 36. They receive payment on a contingent basis; the more money they recover from providers, the more the RACs benefit financially. Cmplt. ¶ 36; *see St. Francis*, 874 F. Supp. 2d at 129.

Because RACs are paid on contingency, their claim-review strategies focus on high-dollar improper payments. Cmplt. ¶ 41; *Project Evaluation* 18. One such high-dollar item is inpatient hospital care, which, depending on the care provided, can cost tens of thousands of dollars per patient. Cmplt. ¶ 41. During the RAC Demonstration Project, fully 41 percent of the purported "errors" the RACs found involved situations where medical services supposedly were provided in the wrong setting. Cmplt. ¶ 42. That often meant that—according to the RACs—hospitals could have provided services on an outpatient basis rather than on an inpatient basis. Cmplt. ¶ 42.

2. The Payment Denial Policy. The RACs err with disturbing regularity in their assertions about whether a patient should have been admitted to the hospital months or years earlier. Cmplt. ¶ 44. Indeed, hospitals report that when they pursue appeals through the administrative appeals process—an expensive and burdensome exercise—they are successful in overturning RAC denials *72 percent* of the time. Cmplt. ¶ 44. Despite this alarming error rate, when a RAC determines that a provider was paid for inpatient hospital services but that the patient should have been treated as an outpatient, CMS takes back the entire Part A payment. Cmplt. ¶ 45. And until March 13, 2013, CMS had long taken the position that when an inpatient claim that was paid under Part A was later taken back, the hospital could then receive Part B payment for only a few ancillary services like diagnostic tests, surgical dressings, and splints. *See* MBPM Chapter 6

§ 10. It could *not* be paid under Part B for the emergency room services, drugs, nursing services and surgical procedures that often comprise the bulk of the care. *See id.* That position is what plaintiffs refer to as CMS's "Payment Denial Policy."

As a result of the Payment Denial Policy, when a RAC concluded that a hospital should have provided items and services on an outpatient, rather than an inpatient, basis, the hospital received little if any reimbursement for the reasonable and medically necessary care provided to the patient. Cmplt. ¶ 46. That was so even though in many cases, the care that would have been provided to that patient on an outpatient basis is the same as the care the patient received as an inpatient. Cmplt. ¶ 46. Take, for example, the Trinity Health case set forth in the Complaint. Cmplt. ¶¶ 104-116. A 60-year-old disabled Medicare beneficiary was admitted to a Trinity Health hospital for stent placement to treat coronary atherosclerosis. Cmplt. ¶ 111. The Trinity Health hospital submitted a request for Part A reimbursement on his behalf. A CMS contractor approved the Part A claim and paid the hospital $18,979. Cmplt. ¶ 111. Some three years later, after reviewing the patient's medical records, the RAC determined that he should not have been admitted as an inpatient; instead, he should have been an outpatient. Cmplt. ¶ 112. The Trinity Health hospital was required to repay the entire $18,979, even though no one disputed that the care provided to the patient was reasonable and medically necessary. Cmplt. ¶ 112.

CMS never articulated a reason for this refusal to pay hospitals under Part B for items and services everyone agreed were reasonable and medically necessary. Cmplt. ¶ 49. Nonetheless, it continued for years to adhere to the Payment Denial Policy, telling hospitals and CMS contractors over and over again that Part B payment was not permitted after a Part A denial other than for the small subset of ancillary items listed in MBPM Chapter 6 § 10, and that there were "no exceptions"

to this rule. CMS, *Frequently Asked Questions No. 2519*;[1] *see also, e.g.*, *CMS Manual System Pub. 100-04 Medicare Claims Processing* 2 (Sept. 17, 2004).[2] Accordingly, almost no hospitals ever sought payment under Part B after a Part A claim denial. Cmplt. ¶ 53. Following CMS's instructions under the Payment Denial Policy, they reasonably concluded that to do so would be a waste of time and resources. Cmplt. ¶ 53.

D. CMS Repudiates The Payment Denial Policy

Plaintiffs brought this action late last year to put an end to CMS's Payment Denial Policy. Plaintiffs asserted in their initial complaint that the Payment Denial Policy was unlawful for at least three reasons: (1) it was contrary to the Medicare Act, (2) it was arbitrary and capricious, and (3) it was invalid for lack of notice-and-comment rulemaking. Cmplt. ¶ 54. After Plaintiffs filed their First Amended Complaint, this Court set a procedural schedule that called for CMS to file the administrative record by March 15, 2013. Cmplt. ¶ 55.

CMS did not file the administrative record on March 15. Instead, on March 13, it repudiated the Payment Denial Policy. CMS simultaneously issued two documents that day: Ruling 1455-R, which set forth an interim policy to handle rebilling after Part A denials, effective immediately,[3] and a proposed rule to address these types of claims going forward, *see Medicare Program; Part B Inpatient Billing in Hospitals*, 78 Fed. Reg. 16,632 (Mar. 18, 2013). CMS effectively conceded in these documents that its longstanding Payment Denial Policy was unlawful. Cmplt. ¶ 57. It wrote in the proposed rule:

> Having reviewed the statutory and regulatory basis of our current Part B inpatient payment policy, we believe that, *under section 1832 of the [Social*

[1] *Available at* https://questions.cms.gov/faq.php?id=5005&faqId=2519.

[2] *Available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R301CP.pdf.

[3] *Available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/Downloads/CMS1455R.pdf.

> *Security] Act, Medicare should pay all Part B services that would have been reasonable and necessary (except for services that require an outpatient status) if the hospital had treated the beneficiary as a hospital outpatient rather than treating the beneficiary as an inpatient*, when Part A payment cannot be made for a hospital inpatient claim because the inpatient admission is determined not reasonable and necessary under section 1862(a)(1)(A) of the Act. [78 Fed. Reg. at 16,636 (emphasis added)].

Though the Secretary now weakly attempts to deny CMS's concession of error,[4] the agency's statement was fundamentally the position plaintiffs articulated in their Complaint. Cmplt. ¶ 57.

Despite repudiating the Payment Denial Policy, however, CMS did not propose to make hospitals whole, either for pre-existing and current claims or in future cases. Cmplt. ¶ 58. The agency explained that Ruling 1455-R "serve[s] as [a] precedential final opinion[ ], order[ ] and statement[ ] of policy and interpretation" that is "binding on all CMS components," including contractors, QICs, ALJs, and the DAB. Ruling 1455-R at 1. And it announced that under the ruling, CMS will process claims that are rebilled under Part B after a Part A denial—and will not apply the Payment Denial Policy or the one-year time limit that generally applies to new Part B claims—in two categories of cases, thus allowing hospitals to obtain the Part B payment to which CMS itself says they are entitled. First, CMS will let hospitals rebill under Part B in new cases that arise while the rulemaking is under way—that is, cases where the Part A denial issues between March 13, 2013 and the effective date of a new rule. *See id.* at 7–8. Second, CMS will allow rebilling where the Part A denial issued prior to March 13, 2013, but the timeframe to appeal that denial has not expired or an appeal is still pending. *See id.* CMS will not, however, allow rebilling of Part A denials for which the timeframe to appeal has already expired. *See id.* at 8.

[4] The Secretary protests that when CMS wrote that "under section 1832 of the [Social Security] Act, Medicare should pay all Part B services that would have been reasonable and necessary," it was simply making a "policy judgment" that such payment is a good idea, not stating its belief that the statute requires that result. Def. Mem. 16 n.3. That is, to put it mildly, an implausible understanding of CMS's statement. When an agency states that is has "reviewed the statut[e]" and concluded based on that review that it "*should pay*" for a service, the only natural reading is that the agency understands, just as plaintiffs contended, that the statute compels that result.

CMS certainly *could* have authorized rebilling for such claims. As we explain below, the agency's procedures authorize providers to adjust bills to make just the sort of technical changes required to obtain payment under Part B—namely, switching the billing category—and do not impose the one-year claim-filing time limit in such cases, given that supplemental bills are not new "claims" at all. *Infra* at 33-34. Even if CMS were to insist on requiring providers to submit new Part B claims, CMS could create an exception to the one-year time limit for filing those claims. And yet CMS chose, without explanation, not to extend Ruling 1455-R to older RAC denials. In so doing, it absolved itself of responsibility to make providers whole in the vast majority of RAC clawback cases. After all, most such cases are no longer live on appeal. Cmplt. ¶ 60.

Moreover, CMS also limited Part B rebilling in a second way: Even for those claims that can be rebilled, CMS will not pay for certain services that CMS deemed to require an "outpatient status," such as observation services. *See* Ruling 1455-R at 6. CMS wrote that even though the contractor's Part A denial in all of these cases overturns the physician's decision to admit the patient as an inpatient, the patient nevertheless technically remains an "inpatient," and thus the hospital cannot bill under Part B for items or services that require an "outpatient status." *Id.*

Ruling 1455-R thus fails to give hospitals back most of what they lost under the Payment Denial Policy. Cmplt. ¶ 62. For most Part A denials issued more than a few months ago, hospitals will never be paid for the services they provided. Cmplt. ¶ 62. The plaintiff hospitals in particular will never be paid for tens of millions of dollars' worth of care they provided to patients, even though all agree that the care was reasonable and necessary. Cmplt.¶¶ 69-126.

E. Plaintiffs' Amended Complaint

On April 19, 2013, plaintiffs filed a Second Amended Complaint alleging, among other things, that CMS's refusal to allow rebilling in most Part A denial cases is arbitrary and capricious

and that CMS is estopped from taking that position given that it induced plaintiffs not to seek Part B payment in the first place by telling them it was unavailable. Cmplt. ¶¶ 148-173. They alleged, in other words, that CMS is not at liberty simply to refuse to compensate hospitals for hundreds of millions of dollars' worth of care that CMS (i) concedes was reasonable and medically necessary and (ii) concedes that it should have paid for under Part B. *Id*.

Before doing so, however, plaintiffs presented particular requests for payment under Part B in cases involving older RAC Part A denials to the agency, as required by the Medicare Act. *See infra* at 19; *see also* 42 U.S.C. § 405(g). For example, on April 17, 2013, plaintiff Missouri Baptist Sullivan requested Part B payment from a CMS contractor for care provided to a 76-year-old Medicare beneficiary. Cmplt.¶¶ 73-77. Missouri Baptist originally had billed that claim under Part A, and CMS paid the hospital $14,794.60. Cmplt. ¶ 73. But a RAC clawed back the entire Part A payment a year later, concluding that the patient should have been treated on an outpatient basis. Cmplt. ¶ 74. Missouri Baptist understood that under CMS's Payment Denial Policy, it could not obtain payment under Part B, so it did not pursue an appeal or attempt to rebill and seek Part B payment. Cmplt.¶¶ 75-76. It did so after CMS issued Ruling 1455-R. Cmplt. ¶ 77.

The other plaintiffs similarly requested payment under Part B for older RAC Part A denials after CMS issued Ruling 1455-R. For example, in April 2013, plaintiff Munson Medical Center requested Part B payment for the care provided to two different Medicare beneficiaries. Cmplt. ¶¶ 84-87, 89. On April 19, 2013, plaintiff Lancaster General Hospital requested Part B payment for the cardiac catheterization provided to a 79-year-old Medicare beneficiary. Cmplt.¶¶ 96-100. In April 2013, a hospital in the system of plaintiff Trinity Health requested Part B payment for treatment provided to two Medicare beneficiaries. Cmplt.¶¶ 106-114.[5] And on April 4, 2013, a

[5] Due to a miscommunication, the Second Amended Complaint incorrectly recounted several background facts about one Trinity Health Medicare beneficiary. *See* Cmplt. ¶¶ 106-107. The

hospital in the system of plaintiff Dignity Health requested Part B payment for treating an 80-year-old Medicare beneficiary. Cmplt.¶¶ 121-124; Decl. of Le Anne Trachok ¶ 10.

These efforts to rebill are set forth in the Complaint at ¶¶ 73-124. But they only scratch the surface of the efforts plaintiffs have expended to put their requests for Part B payment before the agency. Plaintiffs in fact have rebilled, or attempted to rebill, at least 17 older Part A denials, as set forth in the declarations attached at Exs. A-E. Plaintiffs also have requested Part B payment for services that CMS has called "inherently outpatient" services. *E.g.*, Trachok Decl. ¶ 17; Decl. of Jill Robinson ¶ 20. Those efforts to present their bills have been complicated by the fact that CMS failed to offer its contractors guidance on how to handle these bills for Part B payment in the wake of Ruling 1455-R. *E.g.*, Decl. of Lorelie Lauer ¶¶ 12-13; Robinson Decl. ¶ 14. Plaintiffs nevertheless have persevered, making sure to put their bills before the agency by any means necessary, including by filing hand-typed or facsimile requests to adjust their claims. *See id.*

Plaintiffs have done so despite the fact that, on the face of Ruling 1455-R, their rebilled claims are not eligible for payment. After all, Ruling 1455-R states that it applies—and thus authorizes rebilling—only with respect to (i) RAC Part A denials issued after March 13, 2013, and (ii) RAC Part A denials that issued earlier but are still live on appeal. Ruling 1455-R at 7–8. The plaintiffs' requests for payment under Part B do not fall into either category. Ruling 1455-R also states that there will be no Part B payment for services that require an "outpatient status" and are furnished after the point of admission. Plaintiffs are also seeking payment for those services. And Ruling 1455-R states that it is "binding" on the very contractors to which the plaintiff hospitals submitted their amended bills, as well as on the agency's administrative adjudicators. *Id.* at 1.

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beneficiary in fact was 55 years old, was treated for chest pain, and the amount CMS paid was $1,966.15. These facts are not relevant to Trinity Health Care's legal basis for reimbursement, nor to any of plaintiffs' legal claims. Plaintiffs would be happy to amend the Complaint to reflect these changes should the Court so desire.

F. The Status Of Plaintiffs' Attempts To Rebill

In the two-plus months since plaintiffs presented their requests for Part B payment to the agency, some of those amended bills have gone nowhere.[6] The details of each bill's status are set forth in the declarations attached as Exs. A-E. In short, the declarations demonstrate that some contractors are rejecting the plaintiffs' amended bills as unprocessable; others are rejecting the bills as duplicates of the original Part A claim, even though that Part A claim was removed from the system after the RAC denial; and still others are holding the bills in limbo in the system. In none of those circumstances will the plaintiffs be able to take an appeal within CMS; they have reached the end of the line as far as agency adjudication. *See* 42 C.F.R. § 405.926(n) (no administrative appeals from a finding of untimeliness); *id.* § 405.926(s) (no administrative appeals from rejection of a claim from the contractor's system); Medicare Claims Processing Manual ch. 1 § 80.3.1 ("A claim returned as unprocessable for incomplete or invalid information does not meet the criteria to be considered as a claim, is not denied, and, as such, is not afforded appeal rights.").

For example, on June 20, 2013, Medicare contractor Wisconsin Physician Services (WPS) rejected the request for Part B payment submitted by Missouri Baptist and described in ¶ 73 of the Complaint. Decl. of Amber Haring ¶ 13. WPS rejected the request for Part B payment on the basis that the dates listed on the bill are the same as those of the original inpatient admission, meaning that the contractor views the bill as a duplicate to the original Part A claim. *Id.* But that cannot be correct—the RAC already denied payment under Part A and removed the Part A claim from the system, such that there cannot be two bills for the same services. *Id.* ¶ 14. Nor could the hospital ask the contractor to cancel the Part A claim to make clear that it is requesting payment solely

[6] Several amended bills in fact have been paid, or appear to be designated for payment, by the Medicare contractors. *See* Trachok Decl. ¶ 12; Lauer Decl. ¶ 14. The contractors have not explained why they are paying on claims that are not eligible for rebilling under CMS's policy. Plaintiffs expect, based on prior experience, that the contractors will take back at least some of these payments once they realize the payments fail to comport with CMS guidance. *See id.*

under Part B, again because the Part A claim has already been removed from the system. *Id.* ¶ 15. There is no way for Missouri Baptist to make WPS process its request. *Id.* ¶ 16.

Likewise, as of June 25, 2013, WPS has refused to process the request for Part B payment submitted by Munson Medical Center and described at ¶ 84 of the Complaint. Robinson Decl. ¶¶ 10-15. The contractor put the bill in "Return to Provider" status, meaning it is unprocessable. *Id.* ¶ 13. After two conversations with customer service representatives at WPS, and attempts to add or alter codes pursuant to their oral instructions, Munson Medical Center's billing staff determined that there was nothing more they could do to make WPS process the claim. *Id.* ¶ 14.

STANDARD OF REVIEW

The Secretary primarily bases her motion on Fed. R. Civ. Proc. 12(b)(1). "Under Rule 12(b)(1), the plaintiff bears the burden of establishing that the court has subject matter jurisdiction." *Eisenberg* v. *Social Sec. Admin.*, 703 F. Supp. 2d 27, 30 (D.D.C. 2010). This Court "must accept as true all factual allegations contained in the complaint when reviewing a motion to dismiss pursuant to Rule 12(b)(1), and the plaintiff should receive the benefit of all favorable inferences that can be drawn from the alleged facts." *Id.* The Court also "may consider materials outside the pleadings in deciding whether to grant a motion to dismiss for lack of jurisdiction." *Jerome Stevens Pharm., Inc.* v. *Food & Drug Admin.*, 402 F.3d 1249, 1253 (D.C. Cir. 2005).

With respect to Counts IV and V only, the Secretary seeks dismissal pursuant to Rule 12(b)(6). "In considering a 12(b)(6) motion to dismiss, a court must accept as true all of the well-pleaded factual allegations contained in the complaint and grant the plaintiff the benefit of all inferences that can be derived from the facts alleged." *Bello* v. *Howard Univ.*, 898 F. Supp. 2d 213, 218-19 (D.D.C. 2012) (quotation marks & citation omitted).

ARGUMENT

In Ruling 1455-R, CMS promulgated two policies of general applicability, both binding on Medicare contractors and adjudicators. First, it ruled that hospitals cannot rebill under Part B unless the RAC Part A denials that stripped away the original payments are newly-issued or live on appeal. Second, it ruled that hospitals cannot rebill for inherently "outpatient services." Plaintiffs seek to challenge both of these policies on the grounds that they are arbitrary and capricious and suffer from other legal defects. Despite the Secretary's assertions, nothing in the law stands in the way of that challenge. Indeed, the Secretary's arguments prove too much: If she is correct, then there will *never* be judicial review of the first of CMS's new policies, because any challenger will be situated just like the hospitals here. This Court should reject the Secretary's attempt to foreclose judicial review of an agency policy of general applicability. The Secretary is "[b]anking on [the] complexity [of the Medicare program] to execute a fancy two-step . . . in the hopes that the Court will defer to her expertise." *Allina Health Servs.*, 904 F. Supp. 2d at 77. This Court should "recognize[ ] both the Secretary's expertise and the flaws in the procedures she defends, with deference to the former but not to the latter." *Id.* And the Court should recognize that the mantra the Secretary repeats in her motion—that if plaintiffs just sit tight, they can receive review through the administrative process—is an empty promise.

I. PLAINTIFFS HAVE SATISFIED THE PRESENTMENT REQUIREMENT, AND THE EXHAUSTION REQUIREMENT SHOULD BE EXCUSED AS FUTILE.

The Secretary's first line of argument is the old saw that in Medicare cases "claimants must . . . fully exhaust any administrative process . . . before there can be judicial review." Def. Mem. 17. Because the plaintiffs here have not obtained rulings from the DAB, the Secretary says, this Court lacks jurisdiction. *Id*. Not quite. The Medicare Act requires as a jurisdictional prerequisite only that claimants *present* their claims to the agency. Plaintiffs here have done so, and the

Secretary does not contend otherwise. By contrast, the requirement that claimants *exhaust* administrative remedies is waivable. *Tataranowicz*¸ 959 F.2d at 272–74. It should be waived here. Plaintiffs' attempts to pursue their claims through the agency have been thwarted at every turn. And even if Plaintiffs could, against all apparent odds, push their claims through the agency-review process, their efforts would be futile because the Secretary has already staked out her position on the legal issues plaintiffs raise. Pursuing those futile agency appeals also would not aid the Court because plaintiffs challenge systemwide policies and thus no factual development is needed. Under established precedent, this is precisely the type of situation where courts excuse plaintiffs from exhaustion and proceed to the merits.

A. Case Law.

The Medicare Act provides for judicial review "after such hearing as is provided in section 405(g) of this title." 42 U.S.C. § 1395ff. "[T]he Supreme Court has read § 405(g) as imposing two prerequisites to judicial review." *Tataranowicz*, 959 F.2d at 272. "The first is that the plaintiff present a claim for the benefits to the Secretary," or, in this case, to the Medicare administrative contractors "who make initial payment determinations on h[er] behalf." *Id.* "The second is that the plaintiff exhaust all administrative remedies available after an initial denial." *Id.* However, there is a critical difference between the presentment and exhaustion requirements: "[T]he presentment requirement is not 'waivable' but . . . the exhaustion requirement is." *Id.* (citing *Mathews* v. *Eldridge*, 424 U.S. 319, 328–30 (1976) and *Weinberger* v. *Salfi*, 422 U.S. 749, 763–65 (1975)); *see also Shalala* v. *Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 23 (2000) (explaining that "individual hardship may be mitigated . . . through excusing a number of the steps in the agency process, though not the step of presentment of the matter to the agency").

B. Plaintiffs Have Satisfied The Presentment Requirement.

The plaintiffs here have satisfied the presentment requirement. Indeed, the Secretary has not even bothered to assert otherwise.

1. 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 by its terms where a claimant presents his or her claim to "the Medicare administrative contractors who make initial payment determinations" for CMS. *Tataranowicz*, 959 F.2d 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); *Action Alliance of Senior Citizens* v. *Leavitt*, 483 F.3d 852, 856-857 (D.C. Cir. 2007) ("*Action Alliance II*") (presentment does not require a "final decision" by the Secretary). But not even that much is required. The Supreme Court has held that a plaintiff satisfied presentment where he answered an agency questionnaire and sent a letter to the agency in response to a tentative determination that his disability had ceased. *See Eldridge*, 424 U.S. at 329; *see also 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 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*"). The D.C. Circuit affirmed, observing that the plaintiffs at first had not satisfied presentment but that their subsequent letter to the agency "cured the jurisdictional defect." *Action Alliance II*, 607 F.3d at 862 n.1.

2. Plaintiffs have satisfied the presentment requirement many times over. First, the plaintiff hospitals have submitted multiple requests to the agency seeking payment under Part B. *See* Cmplt. ¶¶ 77, 87, 89, 100, 109, 114, 124; *see also supra* at 13-14. They accordingly 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 in fact plaintiffs have done more: On April 17, 2013, the AHA sent the Secretary a letter presenting its claims on behalf of its members, including the plaintiff hospitals. *See* Cmplt. ¶ 67. The letter identified the aspects of Ruling 1455-R that plaintiffs are now challenging in this litigation. *Id.* It pointed out that the new policy adopted in Ruling 1455-R fails utterly to make hospitals whole for CMS's longtime application of its concededly unlawful Payment Denial Policy. *Id.* And it demanded that CMS pay hospitals under Part B in situations, like those in the Complaint, that involve RAC Part A denials that are no longer live on appeal. *Id.* 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.

C. Exhaustion of Administrative Remedies Would Be Futile.

Plaintiffs likewise have satisfied the requirements for waiver of exhaustion.

1. The leading D.C. Circuit case on exhaustion in the Medicare context is *Tataranowicz*. The court there explained that courts can and do "excuse[ ] non-compliance" with the exhaustion requirement even in cases "where the Secretary staunchly demands that the claim be dismissed for want of exhaustion." 959 F.2d at 274 (citing *Eldridge*, 424 U.S. at 328; *Mathews* v. *Diaz*, 426 U.S. 67, 76–77 (1976); and *Bowen* v. *City of New York*, 476 U.S. 467, 483 (1986)). And it explained that while the Supreme Court cases have excused exhaustion on several different rationales, the courts are empowered to do so "pure[ly]" on the ground that further administrative proceedings would be futile. *Id.* (citing *Diaz*, 426 U.S. at 76).

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.* at 274. 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.

2. *Tataranowicz* points the way to the proper outcome here. In this case, 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. Indeed, this is an even *stronger* case for futility than *Tataranowicz*, because here CMS (through its contractors) has barred the door to full administrative review, despite plaintiffs' diligent attempts to seek it. We address these points in turn.

a. *Plaintiffs challenge systemwide legal rules.*

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. Plaintiffs instead are challenging a pair of systemwide, generally applicable policy determinations:

(1) that hospitals cannot rebill under Part B after a RAC clawback unless the RAC decision is still live on appeal, and (2) that hospitals cannot rebill under Part B for what CMS has denominated inherently "outpatient services." *See supra* at 11-13. Further factual development in administrative proceedings would have no bearing on these legal claims. Or, as the D.C. Circuit put it, the waiver of further administrative proceedings "will not curtail development of a record useful for judicial review." *Tataranowicz*, 959 F.2d at 275.

Faced with similar challenges to a systemwide CMS "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, 17–18 (D.D.C. 2006); *accord Hall* v. *Sebelius*, 689 F. Supp. 2d 10, 24 (D.D.C. 2009) (exhaustion futile because plaintiffs challenged generally applicable policy and "no facts unique to any of their claims" would change the 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 requirement may be excused where claimant "asserts a systemwide . . . policy . . . which does not depend on the particular facts of the claimant's case") (citation omitted); *Briggs* v. *Sullivan*, 886 F.2d 1132, 1140–41 (9th Cir. 1989). Just so here.

b. *The Secretary has already taken a stand.*

Contrary to the Secretary's assertion, Plaintiffs are not bringing "anticipated claims" or guessing about whether CMS will allow them to rebill. Def. Mem. 18. Rather, they are challenging the Secretary's publicly announced policy and practice squarely *foreclosing* them from rebilling. The Secretary stated in Ruling 1455-R, in no uncertain terms, that she will not permit rebilling of RAC Part A denials that are no longer live on appeal or that involve inherently

outpatient services. Ruling 1455-R at 7-8. And the Secretary certainly has not abandoned those positions in this litigation. Rather, she has doubled down on them, explaining that in her view, hospitals are not entitled to rebill in either scenario. *E.g.*, Def. Mem. 11. The Secretary, in short, "has evidenced a strong stand on the issue in question and an unwillingness to reconsider the issue." *Randolph–Sheppard Vendors* v. *Weinberger*, 795 F.2d 90, 106 (D.C. Cir. 1986). In such circumstances, the D.C. Circuit has recognized, requiring exhaustion is "clearly useless." *Id.*; *accord Califano* v. *Goldfarb*, 430 U.S. 199, 203 n.3 (1977) (plaintiff not required to exhaust administrative remedies where result is pre-determined); *Etelson* v. *OPM*, 684 F.2d 918, 925 (D.C. Cir. 1982); *Hall*, 689 F. Supp. 2d at 24.

The Secretary hopes that the Court will infer that the outcome is not so clear. For all the plaintiffs know, she hints, the agency might ultimately decide in their favor because "[t]he Secretary's regulations governing the limitation period provide for extension upon a ground seemingly similar to that which Plaintiffs allege, *i.e.*, a determination by [CMS] that 'a failure to meet the deadline . . . was caused by error or misrepresentation of an . . . agent of HHS.' " Def. Mem. 19 (quoting 42 C.F.R. § 424.44(b)(1)). That is a handy reference, but the Secretary's own behavior in this case belies the notion that it might aid the plaintiff hospitals here. For one thing, the Secretary insists against all logic that the Payment Denial Policy was *not* "error," and that her recent about-face, so plainly prompted by this litigation, was just one reasonable choice among reasonable choices—merely an agency "chang[ing] its mind." Def. Mem. 16 n.3. For another, the Secretary knew when she issued Ruling 1455-R that hospitals had relied on her prior policy in choosing not to seek Part B payment or otherwise appeal their claims, and yet she instructed her contractors and adjudicators—in a ruling that she said was "binding" on all of them—that hospitals cannot rebill in cases that do not have live appeals. Ruling 1455-R at 1, 7-8.

In short, exhaustion would be useless here because the agency "has made known that its general views are contrary to those of the complainant," *Etelson*, 684 F.2d at 925, and its adjudicators are not "free to disregard [its] ruling," *Tataranowicz*, 959 F.2d at 275.

c. *Plaintiffs' claims are being rejected by CMS's internal administrative process.*

For all these reasons, waiver of exhaustion is warranted. But in fact, the case for waiver is even stronger here than it was in *Tataranowicz* because there is yet another fact cutting in the plaintiffs' favor: CMS has made it impossible for plaintiffs to achieve the exhaustion the Secretary now demands. As set forth *supra* at 15-16, plaintiffs have submitted to CMS's contractors a variety of adjusted and supplemented bills seeking Part B payment. But many of those filings are going nowhere. Some have already been rejected. *See supra* at 15-16. Others are ricocheting around in the contractors' computer systems. *See id*. The list goes on. *See* Exs. A-E. None of these filings is appealable through the CMS review process because claims that are rejected, rather than denied, cannot be administratively appealed. *See, e.g.*, 42 C.F.R. § 405.926(n),(s).

In short, plaintiffs cannot obtain administrative review of their claims, despite substantial and continued efforts to do so. The effect: Plaintiffs are blocked from obtaining judicial review of the Secretary's unlawful policies unless exhaustion is waived. It is difficult to think of a more fundamental consideration militating in favor of exhaustion. And indeed, the courts have so held. *See Schoolcraft* v. *Sullivan*, 971 F.2d 81, 87 (8th Cir. 1992) ("[U]nless exhaustion is waived . . . there will never be judicial review to challenge the actions the [agency] takes at the initial and reconsideration stages. Exhaustion would be futile if the challenged policy could never be judicially reviewed."); *St. Francis*, 874 F. Supp. 2d at 132.

For all of these reasons, exhaustion would be futile. This Court should excuse plaintiffs from meeting the exhaustion requirement.

II. PLAINTIFFS' SUIT IS RIPE.

The Secretary also claims this case is not prudentially ripe. For support, the Secretary rests on a single assertion: that the pending proposed Part B inpatient billing rule, once finalized, will obviate the need for this Court to rule on plaintiffs' challenges. Def. Mem. 20–23. That is wrong. The Secretary does not have the power to promulgate regulations that operate retroactively. As a consequence, the Secretary's proposed rule—whenever it is finalized and whatever it contains—cannot have any effect on the Secretary's preexisting obligation to pay plaintiffs' adjusted bills, which have already been presented for payment. This Court will have to render judgment regardless, and there is therefore no reason for it to stay its hand.

A. For The Claims At Issue Here, The Secretary's Policy Is Final.

As the Secretary recognizes, Def. Mem. 20, the prudential ripeness doctrine "prevent[s] the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies" that may be overtaken by events before the court rules on them. *Nat'l Park Hospitality Ass'n* v. *Dep't of the Interior*, 538 U.S. 803, 808 (2003). In other words, as the D.C. Circuit has put it, invoking the prudential-ripeness doctrine is proper only where "if [the Court] does not decide . . . now, [it] may never need to." *Nat'l Treasury Employees Union* v. *United States*, 101 F.3d 1423, 1431 (D.C. Cir. 1996).

The Secretary asserts this is such a case because the proposed rule, once finalized, will obviate the need for the Court to rule on plaintiffs' challenges. Def. Mem. 20-22. Not so. Finalizing the proposed rule *cannot* have any effect on plaintiffs' already-presented requests for payment. That is because if the Secretary attempted to apply the terms of her finalized Part B rebilling regulation to plaintiffs' already-submitted bills, that would constitute retroactive application of the Part B inpatient billing regulations. *See Bowen* v. *Georgetown Univ. Hosp.*, 488

U.S. 204, 216 (1988) (Scalia, J., concurring) ("[R]ules have legal consequences only for the future."); *Nat'l Petrochem. & Refiners Ass'n* v. *EPA*, 630 F.3d 145, 162-163 (D.C. Cir. 2010) (treating Justice Scalia's *Georgetown University Hospital* concurrence as " 'substantially authoritative' ") (citation omitted). And although an agency can engage in retroactive rulemaking when Congress allows, *see Nat'l Mining Ass'n* v. *Dep't of Labor*, 292 F.3d 849, 859 (D.C. Cir. 2002), the Supreme Court has squarely held that the Medicare Act does not give the Secretary retroactive rulemaking authority. *Georgetown Univ. Hosp.*, 488 U.S. at 213 ("The statutory provisions establishing the Secretary's general rulemaking power contain no express authorization of retroactive rulemaking.")

As the D.C. Circuit has explained, an agency's application of a regulation is unlawfully retroactive if it "takes away or impairs vested rights." *Arkema* v. *EPA*, 618 F.3d 1, 7 (D.C. Cir. 2010). And that is just what the Secretary's application of her someday-to-be-finalized rebilling rule to plaintiffs' previously presented bills would do. It would take away the vested right plaintiffs have to payment of their claims under the law as it existed at the time of submission to the Secretary for payment and subject them to new, more stringent restrictions the Secretary plans to impose in a final regulation. It makes no difference, moreover, that the more-stringent restrictions to which the Secretary proposes to subject hospitals under a final rebilling rule are procedural ones regarding the process of submitting rebilled Part B claims, rather than the substance of whether they may be paid. "Where a rule 'changes the law in a way that adversely affects [a party's] prospects for success on the merits of the claim," it may operate retroactively even if designated 'procedural' by the Secretary." *Nat'l Mining Ass'n*, 292 F.3d at 860 (quoting *Ibrahim v. District of Columbia*, 208 F.3d 1032, 1036 (D.C. Cir. 2000)). In short, the prospect of the Secretary finalizing her proposed rebilling regulation cannot change the need for this Court to

rule on plaintiffs' challenges to the Secretary's refusal to pay their previously presented requests for Part B payment.

The fact that the yet-to-be-finalized regulation *cannot* be applied to the requests for payment plaintiffs already have presented distinguishes this case from the ones the Secretary cites. Def. Mem. 21. In each of those, the challengers attacked an interim agency policy that, once superseded, would no longer have any practical effect on the challengers—rendering their challenges to the interim policy moot. *See Am. Petroleum Inst.* v. *EPA*, 683 F.3d 382, 388-389 (D.C. Cir. 2012) (impending rule would "likely moot the analysis [the Court] could undertake if deciding the case now"); *Util. Air Regulatory Grp.* v. *EPA*, 320 F.3d 272, 279 (D.C. Cir. 2003) (declining to review abstract challenge to interim EPA policy, but noting that if interim policy was enforced against challengers, they "can seek relief" at that time); *Lake Pilots Ass'n, Inc.* v. *U.S. Coast Guard*, 257 F. Supp. 2d 148, 161-162 (D.D.C. 2003) (because pending rule might remedy harms challengers complained of and that rule might make pending challenge academic, case was not prudentially ripe). Here, however, regardless of the content of any final rule, plaintiffs' reimbursement claims will be judged according to the regulations in effect at the time they were presented. *See Georgetown Univ. Hosp.*, 488 U.S. at 213. Final regulations will be completely irrelevant to those claims.

Contrary to the Secretary's contention, then, dismissing this case now will not save the Court any effort in the long run. And there is therefore nothing standing in the way of this Court finding plaintiffs' claims fit for review. Ruling 1455-R has been " 'formalized and its effects felt in a concrete way' " by plaintiffs through the Secretary's denial or anticipated denial of plaintiffs' presented claims. *Wyoming Outdoor Council* v. *U.S. Forest Serv.*, 165 F.3d 43, 50 (D.C. Cir. 1999) (citation omitted).

What is more, "[f]urther administrative process will not aid in the development of facts needed by the court to decide the question it is asked to consider," *N.Y. State Ophthalmological Soc'y* v. *Bowen*, 854 F.3d 1379, 1386 (D.C. Cir. 1988), because the Secretary will refuse to *give* them any further process. Cmplt. ¶¶ 60, 78-79, 90-91, 101-102, 115, 125-126. Indeed, the Supreme Court held in *Reno* v. *Catholic Social Services., Inc.*, 509 U.S. 43, 63 (1993) that when claims are rejected by a front-line functionary pursuant to a challenged regulation and there is no administrative redress within the agency from that rejection, the "challenge should not fail for lack of ripeness." Just so here. Cmplt. ¶¶ 60, 78, 90, 101, 115, 125. Regardless of the actions the Secretary takes in the future, this Court will need to address plaintiffs' claims regarding the Secretary's existing policies that are causing them concrete harms now. This Court should find plaintiffs' claims fit for adjudication.

B. Plaintiffs Will Suffer Significant Harm If Adjudication Is Delayed.

Because " 'there are no significant agency or judicial interests militating in favor of delay, [lack of] hardship cannot tip the balance against judicial review.' " *Nat'l Mining Ass'n* v. *Fowler*, 324 F.3d 752, 756 (D.C. Cir. 2003) (citation omitted). This Court therefore need not address the hardship prong of the test to find plaintiffs' claims prudentially ripe. *See AT&T Corp.* v. *FCC*, 349 F.3d 692, 700 (D.C. Cir. 2003) ("[W]here there are no institutional interests favoring postponement of review, a petitioner need not satisfy the hardship prong."); *accord Action for Children's Television* v. *FCC*, 59 F.3d 1249, 1258 (D.C. Cir. 1995). But that aspect of the test is, in any event, easily met.

The Secretary asserts that the harm to plaintiffs is merely that they have "not been paid taxpayer money they believe is owed to them." Def. Mem. 22. That is both insulting and incorrect. Each of the plaintiffs in this case is a not-for-profit hospital or hospital system that

provides needed care and other important benefits to its community and relies on timely and accurate payment from the Secretary to fund its operations. *See* Cmplt. ¶¶ 15-19. The clawbacks the Secretary's contractors have inflicted on these plaintiffs have caused them significant hardship. For instance, as applied to Missouri Baptist, the Secretary's unlawful policies have resulted in the hospital actually *losing* money on the care it provides to Medicare beneficiaries. Cmplt. ¶ 70. A similar pattern repeats itself with the other plaintiffs. Each has lost hundreds of thousands, even millions, of dollars because of the Secretary's unlawful policies as applied to them. Cmplt. ¶¶ 81, 92, 103, 104, 116, 118, 126. For the Secretary to dismiss these palpable harms as a mere payment dispute dramatically understates the effect that her unlawful policies have had on the plaintiffs and other hospitals. *See Better Government Ass'n* v. *Dep't of State*, 780 F.2d 86, 93 (D.C. Cir. 1986) (case prudentially ripe where agency's policy had a " 'direct and immediate' impact" on "the performance of [the challengers'] primary institutional activities.") (citation omitted).

Plaintiffs' claims are prudentially ripe.

III. THE COURT HAS JURISDICTION TO REVIEW THE POLICIES OF WHICH PLAINTIFFS COMPLAIN.

The Secretary next argues that this Court lacks jurisdiction with respect to Counts I through V because plaintiffs challenge two anticipated CMS actions—refusal to reopen closed claims, and refusal to extend time limits for new claims—and neither of those actions constitutes a "final decision" of the Secretary triggering judicial review. Def. Mem. 24-28. The Secretary's argument fails for two reasons. *First*, it attacks a straw man: Plaintiffs are not challenging a refusal to reopen or a refusal to extend the time limit; they are challenging CMS's systemwide policy of refusing to let hospitals bill for Part B reimbursement that CMS itself admits should have been paid. Either this Court has jurisdiction to hear that challenge now, or no court ever will. *Second*, and in any event, the Secretary mischaracterizes the administrative mechanisms plaintiffs would

use to request Part B payment in particular cases. Plaintiffs would not need to seek reopening or an extension of the time limit. They could instead use CMS's "adjustment billing" procedure, just as CMS's own adjudicators have ordered contractors to do in many similar cases in the past.

A. The Secretary Misconstrues Plaintiffs' Challenge.

1. The Secretary's argument rests on a lone factual premise: that the plaintiffs are "challeng[ing] . . . the anticipated refusal" of CMS "to reopen Plaintiffs' unfavorable Part A payment determinations or extend the limitation period for Plaintiffs' Part B claims." Def. Mem. 24. Proceeding from that premise, the Secretary argues that this Court lacks jurisdiction because refusals to reopen and decisions not to extend a limitations period are not final decisions triggering judicial review under 42 U.S.C. § 405(g). Def. Mem. 25-28 (citing *Califano* v. *Sanders*, 430 U.S. 99 (1977), and *Palomar Medical Center* v. *Sebelius*, 693 F.3d 1151 (9th Cir. 2012)).

The argument fails at its premise. Plaintiffs in fact are not challenging CMS's decision in any one particular case. They are instead challenging a systemwide CMS policy of general applicability: that hospitals with RAC denials and no live appeals cannot be reimbursed under Part B for items and services that *CMS itself* says it must pay for under Part B. That is precisely the sort of systemwide "legal issue" that the D.C. Circuit found to be appropriate for judicial cognizance in *Tataranowicz*. *See* 959 F.2d at 328. And if this Court accepts plaintiffs' request to excuse exhaustion, plaintiffs will have the "final decision" that gives this Court jurisdiction. 42 U.S.C. § 405(g). After all, "[t]he Secretary's 'final decision' . . . consists of two components, a presentment requirement and an exhaustion requirement." *Ryan*, 12 F.3d at 247. The hospitals have satisfied the first, *see supra* at 19-20, and have demonstrated that the second should be excused, *see supra* at 20-24. That is enough to satisfy the "final decision" requirement. The legal issue plaintiffs raise is properly before the Court.

2. The Secretary seeks to view this case through a different lens: She focuses on the *responses* she might offer to plaintiffs' argument on the merits, rather than on what the plaintiffs are actually challenging. Def. Mem. 24-28. Because one response might be to characterize each individual plaintiff's claims as an attempt to reopen, she argues, the Court has no jurisdiction.

That approach misses the mark for several reasons. First, it bears no resemblance to the actual policy the Secretary adopted; Ruling 1455-R did not rest its temporal distinction on the need for reopening or time extensions, but instead simply announced it with no explanation: one category of hospitals can rebill, and another cannot. *See* Ruling 1455-R at 7-8.

Second, the Secretary's approach fails to align with this Court's precedents, which analyze whether the Court has jurisdiction over the plaintiffs' claims based on the nature of the *claims themselves*, not the Secretary's potential responses. *See, e.g.*, *Tataranowicz*, 959 F.2d at 328 (claims cognizable because they involve "legal issues"); *Hall*, 689 F. Supp. 2d at 24 (claims cognizable because they challenge a "policy . . . or practice of general applicability").

Third, the Secretary's attempt to characterize this case in the manner least friendly to judicial review flies in the face of the D.C. Circuit's recent teachings about the availability of judicial review in Medicare actions. In *Council for Urological Interests* v. *Sebelius*, 668 F.3d 704 (D.C. Cir. 2011), the Court of Appeals considered the Secretary's argument that "a whole category of affected parties" should be foreclosed from seeking judicial review of their legal claims because they had "no way to obtain review"—and thus no way to obtain a final agency decision—"through Medicare Act channels." *Id.* at 708. The court rejected that approach in strong terms. It began by reciting "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 709 (quoting

Michigan Acad., 476 U.S. at 670). It explained that "[t]o overcome this presumption, the government bears a heavy burden." *Id.* (citation omitted). The government must, for example, "point[ ] to specific language or specific legislative history that is a reliable indicator of congressional intent" to deny review. *Id.* (citation omitted). And it held that the Secretary had failed to "overcome the presumption" in the case before it. *Id.* It wrote:

> Critical to our analysis, the Supreme Court has understood section 405(h) as having only channeling force, not, as the government would have it, foreclosing force. *See Ill. Council*, 529 U.S. at 19 (characterizing section 405(h) as "a channeling requirement, not a foreclosure provision—of 'amount determinations' *or anything else*," and drawing a distinction "between a total preclusion of review and postponement of review"); *Mich. Acad.*, 476 U.S. at 680 (finding no evidence of congressional intent to foreclose statutory and constitutional challenges to Medicare regulations).

Id. (some citations omitted; emphasis in *Council for Urological Interests*).

That cuts strongly in favor of construing plaintiffs' challenge as *plaintiffs* bring it, not as the Secretary seeks to rewrite it. After all, the Secretary's approach—deeming this legal challenge nothing more than a reopening case writ large, and putting it beyond the scope of judicial review—would create the "total preclusion of review" that the D.C. Circuit criticized. *Id.* No hospital could ever challenge the systemwide policy CMS adopted in Ruling 1455-R, because in every case the agency could treat its challenge as a simple reopening claim and deny it, thus putting the issue to rest before a court could ever have its say. This Court should reject that approach. There is "no evidence of congressional intent" to place generally applicable policy rulings such as Ruling 1455-R beyond judicial review. *Id.* (citing *Mich. Acad.*, 476 U.S. at 680).

B. Plaintiffs Need Not Seek Reopening Or An Extension Of Time In Order To Rebill.

In any event, even if the Secretary's characterization of plaintiffs' claims controlled the availability of judicial review—which it does not—the outcome would be the same because the

Secretary's characterization is wrong. Not one of the hospital plaintiffs is seeking to reopen its denied Part A claims. *See* Cmplt. ¶¶ 77, 87, 89, 100, 109, 111, 114, 124. Nor need plaintiffs seek an extension of time to file a new Part B claim. Instead, plaintiffs are simply seeking to adjust or supplement their original, timely filed Part A claims to follow the billing format, coding, and data requirements that CMS requires for payment under Part B. CMS's own manuals and a long line of CMS adjudicative decisions make abundantly clear that such an adjustment bill is a permissible procedure, distinct from reopening, that does not create a new "claim" and therefore does not trigger the time limitations to which the Secretary refers. The Secretary's argument that she has foreclosed judicial review by regulation fails for this reason too. Even assuming *dubitante* that the Secretary actually could foreclose judicial review of the whole list of agency decisions set forth in 42 C.F.R. § 405.926, *see* Def. Mem. 26–28, decisions rejecting attempts to adjust bills are not on that list. The Secretary certainly cannot foreclose judicial review by silence.

1. CMS policy has long permitted hospitals to submit "adjustment bills" as the "most common mechanism for changing a previously accepted bill." *See* CMS, Medicare Claims Processing Manual ("MCPM"),[7] 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). An adjustment bill is a distinct billing procedure from a request for reopening. And it is used for a distinct purpose. Where a hospital seeks only to "correct or supplement" incorrect "information" on the original bill, it may submit an adjustment bill. MCPM ch. 3 § 50 (emphasis added). By contrast, where the hospital seeks to add items and services *omitted* from a previously processed bill, it cannot submit an adjustment bill; instead, it must seek reopening. *See* MCPM ch. 3 § 50; *id.* ch. 34 § 10.

[7] *Available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS018912.html?DLPage=1&DLSort=0&DLSortDir=ascending.

CMS fully understands the differences between these distinct procedures. For years, CMS has had separate policies governing the circumstances in which a Medicare contractor should allow each of these two types of requests, established in separate chapters of the MCPM, and has provided separate technical instructions for processing each type of request. *Compare* MCPM ch. 1 §§ 130.1.2.2, 130.1.2.3 *and id.* ch. 3 §§ 50, 50.1, 50.2 (describing the circumstances in which adjustment requests require additional follow-up by the Medicare contractor), *with id.* ch. 34 §§ 10, 10.4 (defining a reopening). CMS's policy manuals make clear that the two tools are not interchangeable. *See* MCPM ch. 34 § 10.4.1; *see also* CMS Transmittal No. 1069 (Sept. 29, 2006).[8] Indeed, CMS's own instructions to its contractors plainly state that hospitals need not request a reopening when there is another mechanism available for correcting their claims:

> Part A providers that are able to submit an adjusted or corrected claim to correct an error or omission may continue to do so and *are not required to request a reopening*. Additionally, we encourage [Medicare contractors] who were handling the corrections of such errors by advising providers to submit adjusted claims to instruct providers that submitting adjusted claims continues to be the most efficient way to correct simple errors.

MCPM ch. 34 § 10.4.1 (emphasis added). Nor do adjustment bills implicate timely claim-filing requirements. An adjustment bill is not a new *claim* at all; rather, it corrects or adds more detailed information already reflected in the original claim.

2. Here, plaintiffs' requests to supplement their originally-submitted Part A claims can and should be processed using adjustment billing procedures. Plaintiffs are not adding new items and services to their original claims for payment under Part A. *See, e.g.*, Haring Decl. ¶ 9; Robinson Decl. ¶ 9. Instead, plaintiffs need make only ministerial or other technical adjustments to satisfy the different bill format, coding, and documentation requirements that CMS has said apply to claims for payment under Part B. *See id.*

[8] *Available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1069CP.pdf.

A long line of decisions by ALJs and the DAB confirms that requests for Part B payment like those submitted by plaintiffs are merely supplements to the original, timely-filed Part A claims and that they can be filed and processed as "adjustment bills." *See, e.g.*, *In re: Hendrick Med. Ctr.*, M-11-410, 2012 WL 2324891, at 4–5 (DAB Apr. 23, 2012) (instructing contractor to use adjustment billing to let hospital rebill under Part B following a RAC Part A denial); *In re: UMDNJ-Univ. Hosp.*, 2005 WL 6290383 (DAB Mar. 14, 2005) (same). Indeed, *Ruling 1455-R itself* acknowledges that the administrative decisions have long used adjustment billing to accomplish rebilling in cases like this one: The ruling stated that it was "adopting (although not endorsing) the decisions of the ALJs and the Medicare Appeals Council that subsequent Part B rebilling by a hospital in situations covered by this Ruling *is supported by concepts of adjustment billing*." Ruling 1455-R at 10 (emphasis added).

3. For all of these reasons, what plaintiffs seek is to adjust their bills, not to reopen their claims. That cuts the rug out from under the Secretary's argument. While the Secretary argues that she can control what constitutes a "final decision" for purposes of 42 U.S.C. § 405(g), and that decisions denying reopening and denying claims as untimely do not count as "final decisions" because the Secretary has made them unreviewable in 42 C.F.R. § 405.926, *see* Def. Mem. 26–28, decisions denying attempts to supplement bills are nowhere to be found in 42 C.F.R. § 405.926. The regulation does not mention adjustment billing, and its provision regarding untimeliness determinations relates only to "fail[ure] to submit a *claim* timely." 42 C.F.R. § 405.926(n) (emphasis added). In that circumstance, the strong presumption in favor of judicial review wins the day. If *congressional* silence cannot foreclose judicial review of agency action, *see Mich. Acad.*, 476 U.S. at 670, it follows *a fortiori* that *agency* silence cannot do the trick either.

4. The Secretary now insists that what plaintiffs seek is necessarily a reopening or a

request for an extension of time to file a Part B claim. Def. Mem. 24-29. To be sure, the Secretary's understanding of her own procedures is generally entitled to some deference. Here, however, that deference does not carry the day for two reasons. First, to plaintiffs' knowledge, the Secretary cannot point to any regulation or other binding document to support the assertion that what plaintiffs seek is necessarily a reopening; that is just the Secretary's litigation-driven *ipse dixit*. This Court need not accept it. *See Miller* v. *Clinton*, 687 F.3d 1332, 1340 (D.C. Cir. 2012) ("[N]ot every kind of agency interpretation, even of a statute the agency administers, warrants *Chevron* deference. We do not, for example, defer to post hoc interpretations contained in agency briefs."). Likewise, the Secretary has not pointed—and to plaintiffs' knowledge cannot point—to any part of the Medicare statute or any regulation to establish that plaintiffs' supplemental information is untimely. Second, Ruling 1455-R itself belies the Secretary's post-hoc assertion that plaintiffs can only seek Part B payment through a reopening. Ruling 1455-R does not use the term "reopening" even once. It likewise does not adopt the *rules* that apply to reopening; for example, it gives hospitals 180 days to request Part B payment after their Part A appeal is denied, *see* Ruling 1455-R at 10-11, whereas CMS regulations give providers one year to seek reopening for any reason, *see* 42 C.F.R. § 405.980(b). If CMS really thought reopening was necessary here, it presumably would have used the rules that apply in reopening cases.

Moreover, even if deference were appropriate, it would have to be weighed against a countervailing consideration of the highest order: "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." *Council for Urological Interests*, 668 F.3d at 709. Allowing CMS simply to pronounce that what plaintiffs seek is a reopening—even though that is not what plaintiff have

asked for—would completely insulate a generally applicable agency policy from review. That is a highly disfavored result, as the D.C. Circuit has made clear.

C. Even If The Secretary Were Correct About Section 405 Jurisdiction, This Court Would Have Jurisdiction Under Section 1331.

In the alternative, even if the Secretary were correct that this Court's jurisdiction turns on the niceties of CMS procedure, *see supra* at 30-32, and even if the Secretary were correct that the plaintiffs' requests for Part B payment cannot be characterized as adjustments to existing bills, *see supra* at 32-36, this Court *still* would have jurisdiction. That is so because plaintiffs' claims for Part B payment would then be new claims. And when CMS rejects a claim and purports to close off all avenues to review, this Court has federal-question jurisdiction under 28 U.S.C. § 1331. *See Am. Chiropractic Ass'n, Inc.* v. *Leavitt*, 431 F.3d 812, 816 (D.C. Cir. 2005).[9]

1. The Secretary correctly states that as a general matter, 42 U.S.C. § 405(h), as incorporated into the Medicare statute by 42 U.S.C. § 1395ii, precludes federal-question jurisdiction over suits arising out of the Medicare Act. *See* Def. Mem. 24. However, that bar on federal-question jurisdiction does not apply in all cases. The D.C. Circuit explained in *American Chiropractic Association* that "[a]lthough § 1395ii, which incorporates § 405(h), would appear to preclude all Medicare suits founded on general federal question jurisdiction, the Supreme Court has recognized an exception: if the claimant can obtain judicial review only in a federal question suit, § 1395ii will not bar the suit." 431 F.3d at 816 (citing *Illinois Council*, 529 U.S. at 10-13, 17-20. "The exception applies not only when administrative regulations foreclose judicial review, but also when roadblocks practically cut off any avenue to federal court." *Id.* "As to the latter, it is not enough that claimants would encounter potentially isolated instances of the inconveniences

[9] The Court need not even 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.

sometimes associated with the postponement of judicial review, or that their claims might not receive adequate administrative attention. The difficulties must be severe enough to render judicial review unavailable as a practical matter." *Id.*

2. If this Court were to accept the Secretary's argument that plaintiffs' claims do not involve adjustment billing, then this case would fall squarely within *American Chiropractic Association.* After all, if plaintiffs' attempt to obtain payment under Part B do not adjust a previous bill, then they constitute a *new* bill—i.e., a new claim for payment under Part B, distinct from the original claim for payment under Part A. And yet the Secretary asserts that a new claim would be untimely, that it would be rejected as such, and that plaintiffs would be blocked from obtaining any administrative or judicial review of that rejection pursuant to 42 C.F.R. § 405.926(n). *See* Def. Mem. 27-28. The Secretary, in other words, squarely asserts that her "administrative regulations [would] foreclose judicial review," would "cut off any avenue to federal court," and would "render judicial review unavailable as a practical matter." *American Chiropractic Ass'n*, 431 F.3d at 816. In that circumstance this Court would have jurisdiction over plaintiffs' suit under Section 1331. *See id.*

Though no more is needed—the D.C. Circuit's holding is of course binding here—decisions from other circuits are to the same effect. In *Furlong* v. *Shalala*, 238 F.3d 227 (2d Cir. 2001), physicians who did not accept Medicare assignments challenged on due process grounds the deprivation of ALJ review of their claims. The Second Circuit relied on the exception carved out in *Illinois Council* to conclude that, in situations where no review under § 405(g) existed over "challenges to agency policy," the claims "fall outside the scope of § 405(h)." *Id*. at 234-236. Accordingly, the court determined that there was jurisdiction and reached the merits. *Id. See also, e.g., Binder & Binder PC* v. *Barnhart*, 399 F.3d 128, 131 (2d Cir. 2005) (citing *Illinois*

Council and observing that "where there is no appropriate administrative forum, it makes no sense to bar federal suit. We presume, after all, that Congress did not intend to foreclose *all* avenues of judicial review."); *Binder & Binder PC* v. *Barnhart*, 481 F.3d 141, 150 (2d Cir. 2007) (on appeal after remand) ("Binder may invoke federal question jurisdiction under 28 U.S.C. § 1331 because, were such jurisdiction unavailable, it would be unable to obtain any judicial review of its claims under the [Social Security] Act."). Just so here. If the Secretary were correct that there is no way to challenge an untimeliness finding via Section 405 jurisdiction, then the plaintiffs "may invoke federal question jurisdiction under 28 U.S.C. § 1331." *Binder & Binder*, 481 F.3d at 150.

IV. *AUBURN REGIONAL* DOES NOT FORECLOSE THE EQUITABLE ESTOPPEL AND EQUITABLE TOLLING CLAIMS.

The Secretary argues in the alternative that Counts IV and V of the Complaint should be dismissed because those counts seek equitable tolling and equitable estoppel and "[a]s a matter of law the Court does not have the power to grant either request." Def. Mem. 30-31. That is so, according to the Secretary, because the Supreme Court in *Sebelius* v. *Auburn Regional Medical Center*, 133 S. Ct. 817 (2012), declined to apply equitable tolling in the context of 42 U.S.C. § 1395oo(a)(3)'s time limit for a provider to appeal to the Provider Reimbursement Review Board (PRRB). As far as the Secretary is concerned, the logic that drove *Auburn Regional* "applies with equal force to the limitation period for filing payment claims," and accordingly Counts IV and V fail on their face. Def. Mem. 31.

This argument fails twice over. To begin with, *Auburn Regional* is about only equitable *tolling*; it says nothing about *estoppel*. The Secretary cannot sensibly argue that *Auburn Regional* requires dismissal of a claim (Count IV) that seeks to equitably estop CMS. Cmplt. ¶¶ 167-173.

But the Secretary fares no better in her attempt to wield *Auburn Regional* against Count V. In *Auburn Regional*, the Supreme Court declined to apply equitable tolling for a very specific

reason: Congress had authorized the Secretary to decide whether to extend the time limit for filing PRRB appeals, and the Secretary by regulation had adopted a hard-and-fast three-year time limit, with no exceptions. *See* 133 S. Ct. at 826. The existence of that hard cap convinced the Court that applying equitable tolling would be contrary to congressional intent (since Congress had given the Secretary the authority to adopt its unmovable time bar). *Id.* The Court explained: "The Secretary allowed only a distinctly limited extension of time to appeal to the PRRB. . . . Imposing equitable tolling to permit appeals barred by the Secretary's regulation would essentially gut the Secretary's requirement that an appeal to the Board 'shall be dismissed' if filed more than 180 days after the NPR, unless the provider shows 'good cause' and requests an extension *no later than* three years after the NPR." *Id.* (emphasis in original).

The key fact that drove *Auburn Regional* is conspicuously absent here. In the context of claims for payment, the Secretary did not use her statutory authority to adopt the sort of hard-and-fast time limit on which the Supreme Court placed so much weight. Instead, the Secretary set forth a *non-exhaustive* list of circumstances in which CMS will extend the time to file, *see* 42 C.F.R. § 424.44(b) ("Exceptions to the time limits for filing claims include the following . . ."), and many of those enumerated circumstances have no time limits at all, *see id.* Equitable tolling here accordingly would not "essentially gut" the Secretary's time limits at all. *Auburn Regional*, 133 S. Ct. at 826. The Secretary's effort to expand *Auburn Regional* into some sort of categorical rejection of equitable tolling fails.

V. THE COURT HAS JURISDICTION OVER COUNT VI.

Finally, the Secretary's motion to dismiss Count VI, *see* Def. Mem. 31-32, fails for largely the same reasons already discussed.

1. Count VI of the Complaint challenges CMS's newly-minted "outpatient status" distinction. In Ruling 1455-R, the Secretary agreed to let hospitals rebill under Part B after a RAC Part A denial, but it placed two major limitations on that rebilling authorization. The first—that hospitals cannot rebill with respect to RAC denials that are no longer live on appeal—is the subject of Counts I-V, discussed above. The second limitation applies to new RAC denials. It provides that even in cases where hospitals may now rebill, they cannot seek payment for "services [that] specifically require an outpatient status, for example, outpatient visits, emergency department visits, and observation services." Ruling 1455-R at 6. That is so, the Secretary wrote, because a patient who was admitted as an inpatient technically *remains* an inpatient for billing purposes, even after a RAC subsequently determines that he was really an outpatient. *Id.* at 8.

The Secretary, in other words, replaced one arbitrary limitation on rebilling with another. Plaintiffs challenged that policy choice in the Complaint. *See* Cmplt. ¶¶ 179-184. They argued that it is irrational to conclude that a beneficiary retains "inpatient" status even after a RAC has determined that the beneficiary was properly an outpatient all along. *Id.* And they alleged that CMS's refusal to let hospitals rebill for these "inherently outpatient" services violated the Medicare Act, which requires CMS to reimburse providers for all reasonable and medically necessary services provided to beneficiaries. *Id.*

2. The Secretary advances several arguments to dismiss this Count. Most simply regurgitate the Secretary's earlier arguments, and none has merit.

a. The Secretary argues that this Court lacks subject matter jurisdiction to adjudicate Count VI because CMS has not yet made a "final decision" rejecting a rebilling claim from the plaintiff hospitals seeking payment for inherently outpatient services. Def. Mem. 32. That is wrong for the reasons explained *supra* at 19-24: It ignores that the "final decision" requirement

"consists of two components, a presentment requirement and an exhaustion requirement," *Ryan*, 12 F.3d at 247, and that the second of these requirements can be excused. The plaintiff hospitals have satisfied the presentment requirement by rebilling for inherently "outpatient services," *see supra* at 14, and by sending the Secretary a letter demanding that she allow hospitals to rebill for those services, *see* Cmplt. ¶ 67; *Action Alliance I*¸ 607 F. Supp. 2d at 37-39. And the exhaustion requirement should be excused here for the reasons already set forth above: The "inherent outpatient services" issue is a systemwide issue of law; no facts specific to individual plaintiffs are required to adjudicate it; the Secretary has taken a position adverse to the plaintiffs on the issue in dispute and "d[id] not argue that the ALJs are free to disregard his ruling"; and the Secretary accordingly has given "no reason to believe that the agency machinery might accede to plaintiffs' claims." *Tataranowicz*, 959 F.2d at 274-75; *see supra* at 20-24.

b. The Secretary argues that plaintiffs do not have standing because they "do not even allege that they . . . have actually submitted or plan to submit any payment claim that they expect to be denied" on the basis of the outpatient-status distinction. Def. Mem. 32. The Complaint, fairly read, does allege just that: It states that CMS will not pay hospitals for services requiring an outpatient status, and it states several times that hospitals have been and will be harmed by the approach adopted in Ruling 1455-R. *E.g.*, Cmplt. ¶¶ 61, 62, 66, 68, 79, 92, 103, 116, 126, 127, 147. But in any event, the Secretary's argument fails because the plaintiff hospitals state in declarations attached hereto that on claims that are covered by Ruling 1455-R, the hospitals in fact have sought payment under Part B for "services [that] specifically require an outpatient status," Ruling 1455-R at 6, and that were provided during the beneficiary's (subsequently denied) inpatient stay. *See supra* at 14. These services include physical therapy, occupational therapy and speech therapy. *E.g.*, Trachok Decl. ¶ 17; Robinson Decl. ¶ 20. Those facts, taken together with

the allegations of the Complaint, suffice to establish that the plaintiffs face "imminent" injury, that there is a "causal connection between the injury and the conduct complained of," and that it is "likely that the injury would be redressed by a favorable decision." *Jack's Canoes & Kayaks, LLC* v. *National Park Serv.*, ___ F. Supp. 2d ___, 2013 WL 1245859, at *7 (D.D.C. 2013) (quotation marks & citations omitted). *See also id.* (courts consider complaint and record facts together in determining whether they have jurisdiction in the face of a Rule 12(b)(1) motion).

c. Finally, the Secretary argues that plaintiffs' challenge to the outpatient-services distinction is "unripe for the same reasons their challenge to the anticipated refusal to revive their expired appeals in unripe, *see* Part I.B., *supra*." Def. Mem. 32. Plaintiffs addressed and refuted this prudential-ripeness argument *supra* at 25-29. The same analysis applies again here.

CONCLUSION

For the foregoing reasons, the Secretary's motion to dismiss should be denied.

Dated: June 27, 2013

Respectfully submitted,

/s/ Catherine E. Stetson

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, MISSOURI BAPTIST SULLIVAN HOSPITAL, MUNSON MEDICAL CENTER, LANCASTER GENERAL HOSPITAL, TRINITY HEALTH CORPORATION, and DIGNITY HEALTH, *Plaintiffs*, v. KATHLEEN SEBELIUS, in her official capacity as Secretary of Health and Human Services, *Defendant*.	Case No. 1:12-cv-1770 (CKK)

DECLARATION OF AMBER HARING

I, Amber Haring, hereby state as follows:

1. I am over the age of 18, and I am competent to testify on the matters set forth herein.

2. I currently serve as the BJC HealthCare Corporate Compliance Manager. I have served at this post since March 2011. The information in this declaration is personally known by me or is derived from information and records maintained by BJC Healthcare, which includes information and records maintained for Missouri Baptist Sullivan Hospital (Missouri Baptist).

3. Missouri Baptist is a not-for-profit hospital providing primary community hospital services to three counties southwest of St. Louis, Missouri. CMS has designated Missouri Baptist as a "critical access" hospital, *i.e.*, a small hospital that provides crucial services to a typically rural community. It is one of 13 hospitals in the BJC HealthCare network, which covers the spectrum of hospitals in terms of size and specialty. Together, BJC HealthCare's

hospitals have 3,445 beds and employ nearly 30,000 people in the greater St. Louis, southern Illinois, and mid-Missouri regions.

4. As the Compliance Manager, it is my responsibility to provide oversight to Missouri Baptist Sullivan regarding Recovery Audit Contractor (RAC) issues, manage all requests received from HealthDataInsights, Inc., the RAC in our geographic region, assure all data are entered into a tracking system, and manage and direct all RAC appeals and re-billing of Part B claims. I am a Registered Health Information Technician (RHIT), which means that I have professional training in ensuring the quality, completeness and accuracy of medical records and reimbursement data.

5. In my role as the Compliance Manager, I coordinate the tasks performed by the BJC HealthCare Patient Accounts and Medical Records independent contractors and worked with billing personnel at Missouri Baptist to help Missouri Baptist submit requests for Medicare Part B payment to Wisconsin Physician Services (WPS), its Medicare administrative contractor, for cases in which a RAC denied payment under Medicare Part A on the ground that, although the care was medically necessary, it should have been provided in an outpatient setting.

6. For example, in 2011, a 76-year-old Medicare beneficiary arrived at the Missouri Baptist emergency room after a week of dizziness, headaches, nausea and vomiting. She was admitted as an inpatient and spent one night in the hospital. Missouri Baptist sought reimbursement under Part A on the patient's behalf. The Medicare contractor approved the Part A claim and paid Missouri Baptist $14,794 for the items and services provided.

7. Almost a year later, in August 2011, after reviewing the patient's medical records, a RAC determined that she should have been treated on an outpatient rather than on an inpatient basis, and demanded that Missouri Baptist repay the entire $14,794. To the best of my

knowledge, at no point during or after the RAC review did anyone dispute that the Medicare beneficiary needed the care that she received or that the hospital had provided only medically necessary items and services.

8. After the Centers for Medicare & Medicaid Services (CMS) issued Ruling 1455-R, I worked with the Patient Accounts and Medical Records personnel departments to request payment under Medicare Part B for the items and services provided to the Medicare beneficiary described above. We confirmed that the beneficiary was enrolled in Medicare Part B.

9. The Medical Records team prepared the requests for Part B payment in accordance with the instructions published by CMS in its policy manuals and by WPS. Among other things, we separately listed revenue codes and Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) codes for each of the items and services that had been provided to the Medicare beneficiary at the hospital. We did not request payment for any items or services in addition to those for which we sought payment under Part A.

10. We presented the request for Part B payment to WPS by manually typing the information described above into a paper form and sending that form to WPS via facsimile on April 17, 2013. That payment request was rejected.

11. After that request was rejected, the Patient Accounts team at my direction used another method to present the request for payment under Part B to WPS, this time by manually typing the information directly into the Medicare claims processing system (known as the Fiscal Intermediary Standard System or FISS) on April 23, 2013. That request was placed in "Return to Provider" status in FISS, meaning that it cannot be processed.

12. After CMS released new instructions in May 2013 for submitting a request for Part B payment, at my direction the Patient Accounts team amended Missouri Baptist's payment request, and on June 13, 2013, again submitted the request to WPS.

13. As of June 20, 2013, WPS rejected this latest request for payment under Part B on the ground that the last service date on the request for payment is the same as or overlaps with the service dates for the original inpatient admission, meaning that WPS views the bill as a duplicate to the original Part A claim.

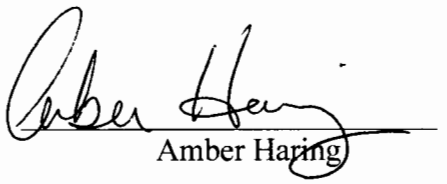
14. To the best of my knowledge, that cannot be correct—the RAC already denied payment under Part A and WPS removed the Part A claim from the Medicare claims processing system, such that there cannot be two bills for the same service dates for the patient described above.

15. To the best of my knowledge, the hospital also cannot ask the contractor to cancel the Part A claim to make clear that the hospital is requesting payment solely under Part B, again because the Part A claim has already been removed from the system.

16. As a result, that means that, to the best of my knowledge, there is no way for Missouri Baptist to get WPS to process the hospital's request for payment under Part B.

17. I do not expect that this request will be paid, as Missouri Baptist received the RAC denial on July 20, 2012 and did not appeal the denial, such that its payment request was submitted past the time period established in Ruling 1455-R for seeking Part B payment for denials that were never appealed.

I make this declaration under penalty of perjury pursuant to 28 U.S.C. § 1746, and I state that the facts set forth herein are true and correct.



Amber Haring

Dated: 6/27/13

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, MISSOURI BAPTIST SULLIVAN HOSPITAL, MUNSON MEDICAL CENTER, LANCASTER GENERAL HOSPITAL, TRINITY HEALTH CORPORATION, and DIGNITY HEALTH, *Plaintiffs*, v. KATHLEEN SEBELIUS, in her official capacity as Secretary of Health and Human Services, *Defendant.*	Case No. 1:12-cv-1770 (CKK)

DECLARATION OF JILL ROBINSON

I, Jill Robinson, hereby state as follows:

1. I am over the age of 18, and I am competent to testify on the matters set forth herein.

2. I currently serve as the Recovery Audit Contractor Senior Biller at Munson Medical Center. I have served at this post since March 1, 2010. The information in this declaration is personally known by me or is derived from information and records maintained by Munson Medical Center.

3. Munson Medical Center (Munson) is a not-for-profit, 391-bed hospital in Traverse City, Michigan. Munson is the largest hospital in the Munson Healthcare System. It employs approximately 4400 people and offers a continuum of health care services in 24 counties across northern Michigan.

4. As the Recovery Audit Contractor Senior Biller, it is my responsibility to process all Recovery Audit Contractor (RAC) denial letters; rebill claims denied by the RAC after review by Munson's medical records and utilization management departments; and track rejections by Medicare, including rejections due to patient ineligibility for Medicare Part B.

5. In my role as the Recovery Audit Contractor Senior Biller, I have personally submitted requests for Medicare Part B payment to Wisconsin Physician Services (WPS), Munson's Medicare administrative contractor, for cases in which a RAC denied payment under Medicare Part A on the ground that, although the care was medically necessary, it should have been provided in an outpatient setting.

6. For example, in 2011, an 89-year-old Medicare beneficiary was admitted as an inpatient at Munson Medical Center after a procedure to repair an esophageal tear and spent one night in the hospital. Because the patient was a Medicare beneficiary, Munson sought reimbursement under Part A on her behalf. The Medicare contractor approved the Part A claim and paid Munson $4,062.83 for the items and services it provided to the patient.

7. In May 2012, after reviewing the 89-year old beneficiary's medical records, a RAC determined that she should have been treated on an outpatient rather than inpatient basis, and Munson was forced to repay the entire $4,062.83. To the best of my knowledge, at no point during or after the RAC review has anyone disputed that the Medicare beneficiary needed the care that she received or that the hospital provided only medically necessary items and services.

8. After the Centers for Medicare & Medicaid Services issued Ruling 1455-R, I worked with others in the Munson billing, medical records and utilization management departments to request payment under Medicare Part B for the items and services provided to the

Medicare beneficiary described above. We confirmed that the beneficiary was enrolled in Medicare Part B.

9. We prepared the requests for Part B payment in accordance with the instructions published by CMS in its policy manuals and by WPS. Among other things, we separately listed revenue codes and Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) codes for each of the items and services that had been provided to the Medicare beneficiary at the hospital. We did not request payment for any items or services in addition to those for which we sought payment under Part A.

10. On April 16, 2013, I presented WPS with Munson's request for reimbursement under Medicare Part B for the care provided to the 89-year-old Medicare beneficiary. In so doing I followed instructions provided by CMS in a Transmittal to Medicare contractors that has since been amended and is set to be implemented, as amended, on July 1, 2013. That request was rejected.

11. On April 24, 2013, after several telephone conversations with WPS about the status of Munson's Part B payment request, I made minor revisions to the bill in accordance with the oral instructions I received from WPS, and re-submitted it to WPS. WPS did not process that request.

12. After CMS released new instructions in May 2013 for submitting a request for Part B payment, I amended Munson's payment request, and on June 5, 2013 I again submitted the request to WPS.

13. On or around June 6, 2013, WPS placed the request in "Return to Provider" status in the Medicare claims processing system, (known as the Fiscal Intermediary Standard System or FISS), meaning that bill is unprocessable.

14. After two separate conversations with customer service representatives at WPS on June 6, 2013, and attempts to add or alter information pursuant to their oral instructions to show that the request for Part B payment is being made after a RAC Part A denial, the request still had not been processed and I concluded that there was nothing more that Munson Medical Center could do to make WPS process it.

15. As of June 25, 2013, WPS has not processed the request for Part B payment submitted by Munson.

16. I also submitted a request for Part B payment for the care provided to another Medicare beneficiary that a RAC determined should have been performed on an outpatient basis. That beneficiary was admitted to the hospital in 2010 for inguinal and femoral hernia procedures. After reviewing the patient's medical records, the RAC determined in April 2012 that the care should have been provided on an outpatient basis, and took back the entire Part A payment of $5938.54.

17. On April 16, 2013, I requested Part B payment for the care provided to this Medicare beneficiary using a different billing format than the bill type that I used for the request described in Paragraph 10 above. On June 6, 2013, I revised Munson's request for payment under Part B to follow the modified instructions released by CMS in May 2013 and re-submitted the request to WPS. On June 20, 2013, this claim was paid in the amount of $1718.24. This payment was unexpected as the hospital received an unfavorable binding appeal decision (an unfavorable reconsideration decision from the qualified independent contractor or QIC) dated September 10, 2012, and the Part B payment request was originally submitted on April 16, 2013, past the 180-day period for seeking Part B payment established in Ruling 1455-R. Based upon my personal experience and the language of Ruling 1455-R, I expect WPS to recoup this

payment. In the past, when contractors have discovered they made a payment error, they simply issue a remittance advance and recoup that payment.

18. I also attempted to request Part B payment for a third Medicare beneficiary that a RAC determined should have received the same care but in the outpatient rather than inpatient setting. For this payment request I used yet another bill format.

19. Specifically, I tried to adjust the bill manually through the Medicare claims processing system to conform to the technical requirements for this particular type of bill, but the limits imposed by the billing system precluded me from doing so. As a result, that request for Part B payment was never entered into the Medicare claims processing system. I also attempted to adjust the bill through an electronic submission, which I expect, but cannot yet confirm, the Medicare claims processing system will not accept.

20. In addition to submitting the above requests for Part B payment, Munson also submitted a request for Part B payment that is within the time period for seeking payment under Ruling 1455-R, but contains a request for payment under Part B for physical therapy, occupational therapy and speech therapy services provided to a 68 year-old Medicare beneficiary after she was admitted to Munson Medical Center for headaches in 2009. I understand that these services are among the inherently "outpatient services" for which Ruling 1455-R limits payment to those beneficiaries with an "outpatient status." As of June 24, 2013, WPS has designated these services for payment, although Munson has yet to receive payment and such payment would be unexpected as the services are excluded from payment under Ruling 1455-R. If WPS pays Munson for these services, based upon my personal experience and the language of Ruling 1455-R, I expect WPS to recoup this payment. In the past, when contractors have discovered they made a payment error, they simply issue a remittance advance and recoup that payment.

I make this declaration under penalty of perjury pursuant to 28 U.S.C. § 1746, and I state that the facts set forth herein are true and correct.

Jill Robinson

Jill Robinson

Dated: 6-27-13

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, MISSOURI BAPTIST SULLIVAN HOSPITAL, MUNSON MEDICAL CENTER, LANCASTER GENERAL HOSPITAL, TRINITY HEALTH CORPORATION, and DIGNITY HEALTH, *Plaintiffs*, v. KATHLEEN SEBELIUS, in her official capacity as Secretary of Health and Human Services, *Defendant*.	Case No. 1:12-cv-1770 (CKK)

DECLARATION OF LORELIE LAUER

I, Lorelie A. Lauer, CPC-H, hereby state as follows:

1. I am over the age of 18, and I am competent to testify on the matters set forth herein.

2. I currently serve as the Manager for Patient Financial Services at Lancaster General Health. I have served at this post since May 29, 2011. The information in this declaration is personally known by me or is derived from information and records maintained by Lancaster General Hospital.

3. Lancaster General Health is an integrated health care delivery system in Lancaster, Pennsylvania that includes Lancaster General Hospital (Lancaster General), a 631-bed, community-based, not-for-profit hospital that employs 7,500 people. Lancaster General Health also offers a freestanding Women & Babies Hospital, multiple outpatient centers, and 40 other health care-related organizations.

4. As the Manager of Patient Financial Services, it is my responsibility to oversee the accurate and complete billing and submission of claims for medical services rendered to patients at Lancaster General Health. This includes ensuring eligibility and compliance with coding and reporting requirements as defined by Medicare Parts A and B for Medicare eligible beneficiaries. This includes rebilling requests identified by internal auditors related to Recovery Audit Contractor (RAC) activities.

5. In that role, I have personally submitted and I have supervised other members of the billing department in submitting requests for Medicare Part B payment to Novitas Solutions (Novitas), Lancaster General's Medicare administrative contractor, for cases in which a Recovery Audit Contractor (RAC) denied payment under Medicare Part A on the ground that the care should have been provided in an outpatient setting.

6. For example, in 2008 a 79-year-old Medicare beneficiary went to Lancaster General Hospital for a scheduled cardiac catheterization. He was admitted as an inpatient and spent one night in the hospital. Lancaster General submitted a request for Part A reimbursement on the patient's behalf. The Medicare contractor approved the Part A claim and paid Lancaster General $8,646.80 for the items and services it provided to the patient.

7. More than three years later, in August 2011, after reviewing the patient's medical records, a RAC determined that he should have been treated as an outpatient. It demanded that Lancaster repay the entire $8,646.80. To the best of my knowledge, after reviewing all of the documents from the RAC and the Medicare administrative contractor related to this denial, at no point during or after the RAC review did anyone dispute that the Medicare beneficiary needed the care that he received or that the hospital had provided only medically necessary items and services.

8. As another example, in 2008 an 82-year-old Medicare beneficiary who had recently undergone heart surgery came to the Lancaster General emergency room with shortness of breath. Diagnostic tests were performed and revealed congestive heart failure. He was admitted as an inpatient and spent one night in the hospital. Lancaster General submitted a request for Part A reimbursement on the patient's behalf. The Medicare contractor approved the Part A claim and paid Lancaster General $2,710.62.

9. More than three years later, in December 2011, after reviewing the patient's medical record, a RAC determined that this Medicare beneficiary should have been treated in an outpatient setting, and Lancaster was forced to repay the entire $2,710.62. To the best of my knowledge, after reviewing all of the documents from the RAC and the Medicare administrative contractor related to this denial, at no point during or after the RAC review did anyone dispute anything other than the setting – inpatient versus outpatient – in which the care was provided.

10. After the Centers for Medicare & Medicaid Services (CMS) issued Ruling 1455-R, I worked with others in the Lancaster General billing and compliance departments to request payment under Medicare Part B for the items and services provided to each of the above beneficiaries. We confirmed at the time of each patient's admission that each beneficiary was enrolled in Medicare Part B.

11. We prepared the requests for Part B payment in accordance with the instructions published by the Centers for Medicare & Medicaid Services (CMS) and by Novitas. Among other things, we separately listed revenue codes and Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) codes for each of the items and services that had been provided to the Medicare beneficiary at the hospital. We did not request

payment for any items or services in addition to those for which we sought payment under Part A.

12. We ultimately presented the requests for Part B payment to Novitas by either electronic claim submission or manually typing the information described above directly into the Medicare claims processing system (known as the Fiscal Intermediary Standard System or FISS) on April 19, 2013. Novitas placed all requests in "Return to Provider" status, meaning the bills are incomplete and need additional information from the provider or else they cannot be processed.

13. For weeks, those requests for payment were trapped in a continuous loop—every few days, Novitas would identify a different technical discrepancy or roadblock. We would work to resolve each of these issues, which could be addressed only one at a time, and would then resubmit the request for payment.

14. As of June 27, 2013, one of Lancaster General's two requests for payment under Part B was still under review by Novitas. The other request has been designated for payment by Novitas, although Lancaster General has not yet received the payment and such payment would be unexpected as the Part B payment request was originally submitted on April 19, 2013, past the time period for seeking Part B payment established in Ruling 1455-R. Based upon my personal experience and the language of Ruling 1455-R, I expect Novitas to recoup this payment. In the past, when contractors have discovered they made a payment error, they simply issue a remittance advance and recoup that payment.

I make this declaration under penalty of perjury pursuant to 28 U.S.C. § 1746, and I stated that the facts set forth herein are true and correct.

Lorelie A. Lauer

Dated: 6/27/2013

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, MISSOURI BAPTIST SULLIVAN HOSPITAL, MUNSON MEDICAL CENTER, LANCASTER GENERAL HOSPITAL, TRINITY HEALTH CORPORATION, and DIGNITY HEALTH, *Plaintiffs*, v. KATHLEEN SEBELIUS, in her official capacity as Secretary of Health and Human Services, *Defendant*.	Case No. 1:12-cv-1770 (CKK)

DECLARATION OF VIVIAN MALLARI

I, Vivian Mallari, hereby state as follows:

1. I am over the age of 18, and I am competent to testify on the matters set forth herein.

2. I currently serve as the Government Manager of Patient Financial Services for Trinity Health-Michigan. I have served at this post since July 1, 2011. The information in this declaration is personally known by me or is derived from information and records maintained by Trinity Health Corporation (Trinity Health).

3. Trinity Health is one of the largest Catholic health care systems in the United States, owning 35 hospitals and managing 12 more. Those hospitals stretch across the country from Maryland to California and employ more than 56,000 full-time equivalent employees.

4. As the Government Manager of Patient Financial Services for Trinity Health-Michigan, it is my responsibility to oversee all Medicare and Medicaid billing for three hospitals that are part of the Saint Joseph Mercy Health System in Michigan: St. Joseph Mercy Oakland, St. Joseph Mercy Port Huron, and St. Mary Mercy Livonia. The personnel that I supervise handle Medicare claims including claims for which a Recovery Audit Contractor (RAC) has denied payment for these three hospitals. I have access to a database that tracks the appeals status of all RAC denials. The team I oversee verifies the patient's eligibility for all claims that are rebilled. Initial Medicare and Medicaid eligibility is verified by the registration staff at each hospital in connection with delivery of care.

5. In my role, I have supervised staff who submitted requests for Medicare Part B payment to Wisconsin Physician Services (WPS), the Medicare administrative contractor for the three Michigan hospitals named above, for cases in which a RAC denied payment under Medicare Part A on the ground that, although the care was medically necessary, it should have been provided in an outpatient setting.

6. For example, in 2009, a 55-year-old disabled Medicare beneficiary was admitted as an inpatient at St. Mary Mercy Livonia hospital to monitor reported chest pain. Because the patient was a Medicare beneficiary, Trinity Health sought Part A reimbursement on his behalf. The Medicare contractor approved the Part A claim and paid Trinity Health $1966.15 for the items and services it provided to the patient.

7. More than a year later, in 2011, after reviewing the patient's medical records, a RAC determined that he should have been treated on an outpatient rather than inpatient basis, and Trinity Health was forced to repay the entire $1966.15. To the best of my knowledge, at no point during or after the RAC review has anyone disputed that the Medicare beneficiary needed

the care that he received or that the hospital provided only medically necessary items and services.

8. At that time, the hospital requested payment under Part B for only the ancillary services, such as laboratory services and diagnostic tests, that CMS allowed to be billed under its prior payment policy. The Medicare contractor paid Trinity Health $733.69, less than half the amount clawed back by the RAC, for the ancillary services that the hospital provided.

9. After the Centers for Medicare & Medicaid Services (CMS) issued Ruling 1455-R, I worked with my staff to request payment under Medicare Part B for the items and services provided to the Medicare beneficiary described above. We confirmed that the beneficiary was enrolled in Medicare Part B.

10. My staff prepared the request for Part B payment in accordance with the instructions published by the Centers for Medicare & Medicaid Services (CMS) in policy manuals and by WPS. Among other things, we separately listed revenue codes and Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) codes for each of the items and services that had been provided to the Medicare beneficiary at the hospital. We did not request payment for any items or services in addition to those for which we sought payment under Part A.

11. On or about April 23, 2013, we first presented the hospital's request for reimbursement under Medicare Part B electronically, by trying to adjust the original Part A claim manually through the Medicare claims processing system to conform with the requirements of one particular bill format, but the limits imposed by the Medicare claims processing system precluded us from doing so. We then presented the payment request via facsimile, using the

same bill format. That effort was similarly unsuccessful in getting the payment request processed.

12. After CMS released new instructions in May 2013 for submitting a request for Part B payment, we amended the hospital's payment request, and on June 26, 2013, we again submitted the request to WPS electronically, using the two different bill formats identified in CMS's instructions.

13. I do not expect that this request will be paid, as the hospital's payment request was submitted past the time period established in Ruling 1455-R for seeking Part B payment for RAC denials that were never appealed.

14. My staff also prepared a request for Part B payment for another Medicare beneficiary that a RAC determined should have been treated on an outpatient, rather than an inpatient, basis. That beneficiary, a 60-year-old disabled man, was admitted to St. Joseph Mercy Oakland hospital in 2008 for stent placement, and spent one night in the hospital. After reviewing the patient's medical records some three years later, a RAC determined in June 2011 that the care should have been provided on an outpatient basis.

15. On or about April 18, 2013, we presented the hospital's request for Part B payment, first using one billing format, and then after we were unable to submit that bill, using a different billing format, again by preparing a paper form and submitting it to WPS by facsimile. WPS did not acknowledge the request and did not upload the payment request into the electronic Medicare claims processing system.

16. After CMS issued the modified instructions in May 2013, we also submitted this payment request to WPS electronically on June 26, 2013.

17. I do not expect that this request will be paid, as the hospital's payment request was submitted past the time period established in Ruling 1455-R for seeking Part B payment for denials that were never appealed.

18. We have also requested Part B payment for three other Medicare beneficiaries who received care at St. Mary Mercy Hospital and St. Joseph Mercy - Oakland that a RAC determined should have received the same care but in the outpatient rather than inpatient setting. For two of these payment requests, we first presented our requests to WPS by facsimile, using one type of billing format, on April 18, 2013. After CMS issued its revised instructions in May 2013, we also submitted all three payment requests to WPS electronically on June 26, 2013, using the two different bill formats identified in CMS's instructions.

19. I do not expect that any of these three requests for Part B payment will be paid, as each of these payment requests was submitted past the time period established in Ruling 1455-R for seeking Part B payment for RAC denials that were never appealed.

I make this declaration under penalty of perjury pursuant to 28 U.S.C. § 1746, and I state that the facts set forth herein are true and correct.

Vivian Mallari

Dated: June 27, 2013

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, MISSOURI BAPTIST SULLIVAN HOSPITAL, MUNSON MEDICAL CENTER, LANCASTER GENERAL HOSPITAL, TRINITY HEALTH CORPORATION, and DIGNITY HEALTH, *Plaintiffs*, v. KATHLEEN SEBELIUS, in her official capacity as Secretary of Health and Human Services, *Defendant*.	Case No. 1:12-cv-1770 (CKK)

DECLARATION OF LE ANNE TRACHOK

I, Le Anne Trachock, hereby state as follows:

1. I am over the age of 18, and I am competent to testify on the matters set forth herein.

2. I currently serve as the Senior Vice President of Finance and Revenue Operations for Dignity Health. I have served in this role since June 2002. The information in this declaration is personally known by me or is derived from information and records maintained by Dignity Health.

3. Dignity Health, one of the nation's five largest health care systems, is an 18-state network of nearly 11,000 physicians, 56,000 employees, and more than 300 care centers, including hospitals (39 in all), urgent and occupational care, imaging centers, home health, and primary care clinics. Headquartered in San Francisco, Dignity Health is dedicated to providing

compassionate, high-quality and affordable patient-centered care with special attention to the poor and underserved. In 2011, Dignity Health provided $1.6 billion in charitable care and services. One of the Dignity Health hospitals is St. John's Regional Medical Center (SJRMC), a 265-bed, community-based hospital in Ventura County, California.

4. As the Senior Vice President of Finance and Revenue Operations, it is my responsibility to ensure the infrastructure, processes, and controls are in place across Dignity Health to facilitate eligibility determinations for Medicare Part A and B, billing Medicare Part A and/or Part B for care provided by Dignity Health hospitals to Medicare beneficiaries, and any activities specifically related to Recovery Audit Contractor (RAC) audits and rebilling requests.

5. In that role, I have established teams and roles that monitor all requests for Medicare Part B payment submitted by Dignity Health hospitals, including SJRMC, to their respective Medicare administrative contractors, for cases in which a RAC denied payment under Medicare Part A on the ground that the care should have been provided in an outpatient setting.

6. For example, in 2008, an 80-year-old Medicare beneficiary arrived at SJRMC to have a pacemaker implanted. He was admitted as an inpatient and spent one night in the hospital. SJRMC sought reimbursement under Part A on the beneficiary's behalf. Palmetto GBA (Palmetto), SJRMC's Medicare administrative contractor, approved the Part A claim and paid SJRMC $14,103.31 for the items and services it provided to the patient.

7. Approximately three years later, after reviewing the patient's medical records, a RAC determined that the 80-year-old Medicare beneficiary should have been treated on an outpatient basis, rather than on an inpatient basis, and SJRMC was forced to repay the entire $14,103.31. To the best of my knowledge, at no point during or after the RAC review has

anyone disputed that the Medicare beneficiary needed the care that he received or that the hospital had provided only medically necessary items and services.

8. After the Centers for Medicare & Medicaid Services (CMS) issued Ruling 1455-R, the appropriate staff from Dignity Health Patient Financial Services requested payment under Medicare Part B for the items and services provided to the Medicare beneficiary described above. We had already confirmed that the beneficiary was enrolled in Medicare Part B.

9. The Dignity Health Patient Financial Services representative prepared the requests for Part B payment in accordance with the instructions published by CMS in its policy manuals and by Palmetto. Among other things, we separately listed revenue codes and Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) codes for each of the items and services that had been provided to the Medicare beneficiary at the hospital. We did not request payment for any items or services in addition to those for which we sought payment under Part A.

10. On April 4, 2013, SJRMC presented Palmetto with its request for reimbursement under Medicare Part B for the care provided to the 80-year-old Medicare beneficiary. The request was denied on the ground that the services were provided on the same day or one day prior to the inpatient admission, meaning that in Palmetto's view, the services should have been bundled into the inpatient stay and paid as part of the Part A payment for that stay.

11. After CMS released new instructions in May 2013 for submitting a request for Part B payment, SJRMC amended its payment request, and on June 13, 2013, again submitted the request for Part B payment to Palmetto.

12. As of June 26, 2013, Palmetto has designated these services for payment, although SJRMC has yet to receive the payment. This payment is unexpected as the hospital

received an unfavorable binding appeal decision (an unfavorable reconsideration decision from the qualified independent contractor or QIC) dated October 31, 2011, and the Part B payment request was originally submitted on April 4, 2013, past the 180-day period for seeking Part B payment established in Ruling 1455-R. If Palmetto pays SJRMC for these services, based upon my personal experience and the language of Ruling 1455-R, I expect Palmetto to recoup this payment. In the past, when contractors have discovered they made a payment error, they simply issue a remittance advance and recoup that payment.

13. Dignity Health also submitted requests for Part B payment on behalf of several of its hospitals for the care provided to five other Medicare beneficiaries that the RAC determined should have been performed on an outpatient, rather than an inpatient, basis.

14. Those requests were initially submitted to each hospital's respective Medicare administrative contractor, (either Palmetto or Noridian), using two different billing formats, on or around April 4, 2013. Two of the requests were rejected out of hand on the ground that the last service date on the request for payment is the same as or overlaps with the service dates for the original inpatient admission, meaning that the Medicare administrative contractor viewed the requests as a duplicates to the original Part A claims. The other three requests were suspended for manual review by the Medicare administrative contractor for unrelated reasons.

15. After CMS released new instructions in May 2013 for submitting a request for Part B payment, Dignity Health amended the five requests for Part B payment and on June 17, 2013, resubmitted them to either Palmetto or Noridian.

16. As of June 25, 2013, one of these five requests had been rejected on the ground that the date on the request for payment is the same as or overlaps with the service dates for the original inpatient admission, and the other four requests remained suspended for manual review

by the Medicare administrative contractor for unrelated reasons. Dignity Health cannot take any additional steps for any of these five payment requests at this time in order to obtain Part B payment.

17. In addition to submitting the above requests for Part B payment, Dignity Health Central Coast also has submitted requests for Part B payment on behalf of two hospitals that are within the time period for seeking payment under Ruling 1455-R, but that contain a request for payment under Part B for physical therapy, occupational therapy and speech therapy services provided to Medicare beneficiaries after they were admitted to the hospital. I understand that these services are among the inherently "outpatient services" on which Ruling 1455-R limits payment to those beneficiaries with an "outpatient status." Nevertheless, one of these claims has been paid by Palmetto. Such payment was unexpected as the services are excluded from payment under Ruling 1455-R. In any case in which Palmetto pays for these services, based upon my personal experience and the language of Ruling 1455-R, I expect Palmetto to recoup this payment. In the past, when contractors have discovered they made a payment error, they simply issue a remittance advance and recoup that payment. The remaining requests are still under review by Palmetto.

I make this declaration under penalty of perjury pursuant to 28 U.S.C. § 1746, and I state that the facts set forth herein are true and correct.

Le Anne Trachok

Dated: 6/27/13

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*, Plaintiffs, v. KATHLEEN SEBELIUS, in her official capacity as Secretary of Health and Human Services, Defendant.	Case No. 1:12-cv-1770-CKK **[PROPOSED] ORDER**

[PROPOSED] ORDER

Upon consideration of the Motion to Dismiss by Defendant Secretary of Health and Human Services, the Memorandum of Points and Authorities in support thereof, Plaintiffs' Opposition thereto, Defendant's reply, if any, and oral argument, if any, and for good cause shown, it is hereby ORDERED that Defendant's Motion to Dismiss is DENIED.

IT IS SO ORDERED.

Dated: ___, ____ 2013

_____

The Honorable Colleen Kollar-Kotelly
United States District Judge

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