No. 11-975

In the Supreme Court of the United States

HENRY FORD HEALTH SYSTEM, DBA
HENRY FORD HOSPITAL, PETITIONER

v.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

Section 5505(b) of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 5505(b), 124 Stat. 660-661, provides that Medicare payments to hospitals for the indirect costs of medical education (IME) shall include "all the time spent by an intern or resident * * * in non-patient care activities, such as didactic conferences and seminars, as such time and activities are defined by the Secretary." Section 5505(b) also provides that, for cost reporting periods beginning on or after October 1, 2001, IME payments shall not include "all the time spent by an intern or resident * * * in research activities that are not associated with the treatment or diagnosis of a particular patient." § 5505(b), 124 Stat. 661; see § 5505(c)(3), 124 Stat. 661.

The question presented is whether the Secretary reasonably exercised her authority under Section 5505(b) to exclude time spent conducting medical research that is not associated with the treatment or diagnosis of a particular patient for cost reporting periods prior to 2001.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-14a) is reported at 654 F.3d 660. The opinion and order of the district court (Pet. App. 15a-48a) is reported at 680 F. Supp. 2d 799. The decision of the Administrator of the Centers for Medicare & Medicaid Services (Pet. App. 49a-76a) is unreported but is available at 2008 WL 6468507. The decision of the Provider Reimbursement Review Board (Pet. App. 77a-103a) is unreported but is available at 2008 WL 7256682.

JURISDICTION

The judgment of the court of appeals was entered on August 18, 2011. The petition for rehearing was denied on November 9, 2011 (Pet. App. 104a-105a). The peti-

tion for a writ of certiorari was filed on February 7, 2012. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. The Medicare program, established by Title XVIII of the Social Security Act, 42 U.S.C. 1395 *et seq*. (Medicare statute or Act), pays for certain medical services provided to elderly and disabled patients entitled to benefits under the program. The Act establishes a Prospective Payment System (PPS) for reimbursement of inpatient operating costs at acute care hospitals, under which such hospitals are paid prospectively at a fixed amount for each patient discharged, regardless of actual costs incurred. See 42 U.S.C. 1395ww(d) (2006 & Supp. IV 2010).

To account for the higher patient care costs incurred by hospitals with medical education programs, the Medicare statute provides special adjustments for teaching hospitals. There are two types of such payments: one for direct graduate medical education (DGME) costs, 42 U.S.C. 1395ww(h) (2006 & Supp. IV 2010), and one for indirect medical education (IME) costs, 42 U.S.C. 1395ww(d)(5)(B) (2006 & Supp. IV 2010). DGME costs include education-related expenses, such as residents' salaries. See 42 C.F.R. 413.75(b)(1). IME costs, which are at issue in this case, include expenses incurred by teaching hospitals due to the additional tests and procedures ordered by residents, as well as the additional demands placed on staff associated with a residency program. See H.R. Rep. No. 25, 98th Cong., 1st Sess. Pt. 1, at 140 (1983); S. Rep. No. 23, 98th Cong., 1st Sess. 52 (1983); 54 Fed. Reg. 40,286 (Sept. 29, 1989); 51 Fed. Reg. 16,775 (May 6, 1986).

The Medicare statute provides a formula for calculating the IME payment that is based in relevant part on the number of "full-time equivalent" (FTE) residents. See 42 U.S.C. 1395ww(d)(5)(B) (2006 & Supp. IV 2010). Through the years, the Secretary has issued a series of implementing regulations specifying which residents count in a hospital's IME calculation. During the cost reporting periods at issue here, the regulations provided that FTE residents are those residents enrolled in an approved teaching program and "working in the portion of the hospital subject to the prospective payment system or in the outpatient department of the hospital." 42 C.F.R. 412.105(g)(1)(i) and (ii) (1991); see 42 C.F.R. 412.105(f)(1)(i) and (ii) (1999).[1]

In 2001, the Secretary amended the IME regulation in order to resolve "some confusion in the provider community as to whether the time that residents spend performing research is countable for the purposes of * * * indirect GME reimbursement." 66 Fed. Reg. 39,896 (Aug. 1, 2001). The new regulation expressly provided that "[t]he time spent by a resident in research that is not associated with the treatment or diagnosis of a particular patient is not countable." 42 C.F.R. 412.105(f)(1)(iii)(B) (2001). The Secretary emphasized that the regulation did "*not* mak[e] a change in policy, but merely clarif[ied]" the agency's "longstanding policy" that IME costs do not include "residents to the extent [they] are not involved in furnishing patient care

[1] For discharges on or after August 10, 1993, a resident assigned to "any entity receiving" a specified grant was also included in the FTE resident count. 42 C.F.R. 412.105(g)(1)(ii)(C) (1996). For discharges on or after October 1, 1997, "the time spent by a resident in a non-hospital setting in patient care activities" was included. 42 C.F.R. 412.105(f)(1)(ii)(C) (1999).

but are instead engaged exclusively in research." 66 Fed. Reg. at 39,897-39,898.

In 2006, the Secretary amended the IME regulation again to add a new paragraph providing that "[i]n order to be counted, a resident must be spending time in patient care activities." 42 C.F.R. 412.105(f)(1)(iii)(C) (2006); see 71 Fed. Reg. 48,094 (Aug. 18, 2006). The regulations defined "[p]atient care activities" as "the care and treatment of particular patients, including services for which a physician or other practitioner may bill." 42 C.F.R. 413.75(b) (2006) (emphasis omitted). The Secretary explained that the amendments were designed to respond to some confusion as to whether certain didactic activities (*e.g.*, conferences, seminars, journal clubs) may be included in the hospital's FTE resident count. 71 Fed. Reg. at 48,080-48,094.

2. On March 23, 2010, Congress enacted the Patient Protection and Affordable Care Act (ACA), Pub. L. No. 111-148, 124 Stat. 119.

a. Section 5505 of ACA amended the statutory calculation of the DGME and IME adjustments in three relevant respects. First, for the IME adjustment, ACA reversed the Secretary's treatment of "didactic conferences and seminars," by mandating their inclusion in the FTE resident count for cost reporting periods beginning on or after January 1, 1983. ACA § 5505(b) and (c)(1), 124 Stat. 660-661. Second, for the IME adjustment, ACA codified the Secretary's treatment of "research activities that are not associated with the treatment or diagnosis of a particular patient," by mandating their exclusion from the FTE resident count for cost years beginning on or after October 1, 2001. § 5505(b) and (c)(3), 124 Stat. 661. Third, for the DGME adjustment, ACA mandated the inclusion of "didactic conferences

and seminars," and the exclusion of "research not associated with the treatment or diagnosis of a particular patient," for cost years beginning on or after July 1, 2009. § 5505(a)(1)(B) and (c)(2), 124 Stat. 660-661.

For cost years prior to 2001, Section 5505 did not speak directly to whether or when research activities that are not associated with the treatment or diagnosis of a particular patient (so-called "pure research") should be included in the IME adjustment. Instead, Congress provided that, for cost years after 1983, "all the time spent by an intern or resident * * * in non-patient care activities, such as didactic conferences and seminars, as such time and activities are defined by the Secretary, * * * shall be counted toward the determination of" FTE. ACA § 5505(b) and (c)(1), 124 Stat. 660-661. In the following paragraph, Congress provided that "all the time spent by an intern or resident * * * in research activities that are not associated with the treatment or diagnosis of a particular patient, as such time and activities are defined by the Secretary, shall not be counted toward the determination of" FTE. § 5505(b), 124 Stat. 661. Congress declared that the latter paragraph applied only to cost reporting periods on or after October 1, 2001, and that it "shall not give rise to any inference as to how the law in effect prior to such date should be interpreted." § 5505(c)(3), 124 Stat. 661.

b. To implement Section 5505(b), the Secretary commenced a rulemaking proceeding. See 75 Fed. Reg. 46,170, 46,387-46,389, 46,464 (Aug. 3, 2010). The Secretary recognized "Congress' clear intent to reverse [the agency's] 2006 policy regarding didactic time and to ratify [its] policy regarding research time from October 1, 2001, forward, while also indicating that it was not directing any result as to research activities before Octo-

ber 1, 2001." 75 Fed. Reg. 71,800, 72,146 (Nov. 24, 2010). On November 24, 2010, after notice and comment, the Secretary promulgated a final rule specifying that, "for cost reporting periods beginning on or after January 1, 1983, except for research activities described in paragraph (f)(1)(iii)(B) of this section," *i.e.*, not associated with the treatment or diagnosis of a particular patient, "the time a resident is training in an approved medical residency program in a hospital setting * * *, must be spent either in patient care activities, * * * or in nonpatient care activities, such as didactic conferences and seminars, to be counted." *Id.* at 72,261 (codified at 42 C.F.R. 412.105(f)(1)(iii)(C)); see 42 C.F.R. 412.105(f)(1)(iii)(B).

In the preamble, the Secretary explained that "[t]here are several unique features of 'research'" that "distinguish it from 'nonpatient care activities,' such as didactic conferences and seminars." 75 Fed. Reg. at 72,144; *ibid.* (noting that Section 5505 makes the same distinction). Didactic conferences and seminars, the Secretary explained, have a more direct connection to the treatment of Medicare patients because they "could include an administrative rotation, which would include resident training in the administrative aspects of medical care such as practice management," *ibid.*; they could "involve presentations or discussions related to the treatment of current patients," *id.* at 72,146; and they could occur "when an intern or resident is otherwise assigned to a rotation primarily requiring the provision of patient care," *ibid.* Pure research, on the other hand, is often performed by interns and residents in discrete blocks of time and, by definition, is "not associated with the treatment or diagnosis of a particular patient." *Id.* at 72,144-72,145. Moreover, the Secretary observed

that, "[f]rom the outset of the Medicare program, [pure] research costs have not been considered reasonable costs of patient care." *Id.* at 72,144.

3. Petitioner, a teaching hospital, applied for Medicare payments for fiscal years 1991-1996 and 1998-1999. In calculating petitioner's IME adjustment, the fiscal intermediary did not include residents engaged in pure research in the hospital's FTE resident count. See Pet. App. 18a-19a. The Provider Reimbursement Review Board (PRRB or Board) reversed, see *id.* at 77a-103a, and the Administrator of the Centers for Medicare & Medicaid Services (CMS), acting on behalf of the Secretary, then reversed the Board, *id.* at 49a-76a. Petitioner sought review in district court contending, among other things, that the Secretary erred in excluding residents involved in pure research from its FTE count. *Id.* at 15a-16a. In a decision issued before the enactment of Section 5505 of ACA, the district court reversed the Secretary and held that the then-governing regulations required the inclusion of pure research. *Id.* at 15a-48a.

4. The Secretary appealed. While the appeal was pending, Congress enacted Section 5505 of ACA and, shortly thereafter, the Secretary adopted implementing regulations. Based on the intervening law, the court of appeals reversed. Pet. App. 1a-14a.

Applying *Chevron U.S.A. Inc.* v. *NRDC*, 467 U.S. 837 (1984), the court of appeals first concluded that Section 5505 of ACA did not "directly answer whether pure research amounts to an eligible 'non-patient care activit[y]' and thus must be counted toward a hospital's FTE calculation." Pet. App. 6a (brackets in original). The court explained that while Section 5505(b) required the Secretary to consider "all the time spent * * * in non-patient care activities * * * in the hospital," *ibid.*

(quoting ACA § 5505(b), 124 Stat. 660-661), that does not answer the question "whether pure research counts," *id.* at 7a. Rather, the court continued, the phrase "non-patient care activities" is not self-defining—particularly when read in context. *Ibid.* As the court explained, Congress expressly delegated to the Secretary the authority to "'define[]' eligible 'non-patient care activities,'" and deemed it necessary to provide two examples of such activities. *Ibid.* (brackets in original) (quoting ACA § 5505(b), 124 Stat. 661). The court thus concluded that "[t]he request to define implies a need to define," and "[t]he legislative impulse to illustrate what this phrase means confirms that it is not self-defining." *Ibid.*

The court of appeals rejected petitioner's arguments to the contrary. The court first determined that petitioner's reliance on Section 5505(a), which addresses "the calculation of a hospital's *direct cost* reimbursements for the time residents spend in certain 'non-provider setting[s],' such as nursing homes or clinics," was misplaced. Pet. App. 9a-11a (brackets in original). Because that provision refers to "non-patient care activities, such as didactic conferences and seminars, but not including [pure] research," petitioner had argued that pure research was necessarily a subset of non-patient care activities. *Id.* at 9a (emphasis omitted; brackets in original) (quoting ACA § 5505(a)(1)(B), 124 Stat. 660). The court, however, deemed it "perfectly sensible" for Congress to specify that pure research is not reimbursable for "direct" costs outside a hospital, "but to allow the Secretary to make the call for 'indirect' costs" inside the hospital. *Id.* at 10a-11a. The court also rejected petitioner's contention that any activity that is not a "patient care" activity is necessarily a "non-patient care" activity for purposes of the IME adjustment because, the court

explained, "the two categories do not define the universe of a resident's activities." *Id.* at 11a.

At the second step of the *Chevron* analysis, the court of appeals concluded that the Secretary had "acted within her authority by excluding pure research from 'non-patient care activities, such as didactic conferences and seminars.'" Pet. App. 12a. The court explained that "[t]he Secretary may reasonably believe that Medicare primarily focuses on patient care, not medical research," and that "[s]he thus may be willing to reimburse only those non-patient care activities that seem to benefit current patients." *Ibid.* Indeed, the court observed, Congress adopted precisely "the same view in dealing with non-patient care activities outside of a hospital in [Section] 5505(a)." *Ibid.*

ARGUMENT

The decision of the court of appeals is correct and does not conflict with any decision of this Court or any other court of appeals. The question presented also impacts relatively few cases and is of limited prospective importance. Further review is not warranted.

1. Section 5505(b) provides that "all the time spent by an intern or resident * * * in non-patient care activities, such as didactic conferences and seminars, as such time and activities are defined by the Secretary" shall be counted toward the determination of a hospital's FTE resident count. ACA § 5505(b), 124 Stat. 660-661. The court of appeals correctly held that the Secretary reasonably exercised her express statutory authority to "define[]" countable "non-patient care activities" to include didactic conferences and seminars, but to exclude research activities that are not associated with the treatment or diagnosis of a particular patient.

a. Contrary to petitioner's contentions (Pet. 21-30), Section 5505 does not directly answer whether pure research amounts to an eligible "non-patient care activit[y]" that must be included in a hospital's FTE resident calculation for cost reporting periods prior to 2001. The court of appeals therefore correctly concluded (Pet. App. 6a-11a) that step one of *Chevron* does not resolve the question presented.

In amending the IME and DGME adjustments, Congress conclusively resolved several issues regarding which activities should be included as part of the hospital's FTE resident count. First, for the IME adjustment, Congress directed that "didactic conferences and seminars" must be included in the FTE count for cost reporting periods beginning on or after January 1, 1983. ACA § 5505(b) and (c)(1), 124 Stat. 660-661. That amendment reversed the Secretary's policy of excluding *all* activities unrelated to patient care from the FTE count. See, *e.g.*, 42 C.F.R. 412.105(f)(1)(iii)(C) (2006). Second, for the IME adjustment, Congress directed that research activities not associated with the treatment or diagnosis of a particular patient must be excluded from the FTE resident count for cost years beginning on or after October 1, 2001. ACA § 5505(b) and (c)(3), 124 Stat. 661. That amendment codified the Secretary's policy of excluding pure research from the FTE count. See, *e.g.*, 42 C.F.R. 412.105(f)(1)(iii)(B) (2001). Third, for DGME purposes, Congress directed that didactic conferences and seminars must be included in the FTE resident count, but that pure research must be excluded, for cost years beginning on or after July 1, 2009. ACA § 5505(a)(1)(B) and (c)(2), 124 Stat. 660-661.

Conspicuously absent from Section 5505 of ACA is any provision expressly dictating how the Secretary

should treat pure research for IME purposes for the cost reporting periods at issue here (*i.e.*, pre-2001). That very question had been the subject of a longstanding and well-known interpretative dispute that had given rise to litigation and to several judicial opinions. Specifically, several teaching hospitals (including petitioner) had argued that the Secretary's pre-2001 regulation required pure research time to be included in a hospital's FTE resident count, whereas the Secretary had consistently interpreted the pre-2001 regulation as excluding such time. At the time of ACA's enactment, the First Circuit had upheld the Secretary's interpretation of the pre-2001 regulation, see *Rhode Island Hosp.* v. *Leavitt*, 548 F.3d 29 (2008); four district courts (including the district court below) had rejected the Secretary's interpretation;[2] this case was pending in the Sixth Circuit, *Henry Ford Health Sys.* v. *Department of Health & Human Servs.*, No. 10-1209 (filed Feb. 22, 2010); and another case was pending in the Seventh Circuit, see *University of Chi. Med. Ctr.* v. *Sebelius*, No. 09-3429 (filed Oct. 1, 2009).

With that backdrop, Congress amended the IME adjustment without speaking directly to the status of pure research for pre-2001 cost reporting periods. And, lest any inference be drawn from its silence, Congress provided that no "inference" should be drawn "as to how the law in effect prior to [October 1, 2001] should be interpreted." ACA § 5505(c)(3), 124 Stat. 661. Congress thus left the appropriate treatment of research activities

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[2] See Pet. App. 15a-48a (2009); *University of Chi. Med. Ctr.* v. *Sebelius*, 645 F. Supp. 2d 648 (N.D. Ill. 2009), aff'd, 618 F.3d 739 (7th Cir. 2010); *Rhode Island Hosp.* v. *Leavitt*, 501 F. Supp. 2d 283 (D.R.I. 2007), rev'd, 548 F.3d 29 (1st Cir. 2008); *University Med. Ctr. Corp.* v. *Leavitt*, No. 05-CV-495, 2007 WL 891195 (D. Ariz. Mar. 21, 2007).

not associated with the treatment or diagnosis of a particular patient for cost years before 2001 to the Secretary and to the courts.[3]

Absent any direct explication as to how pure research should be counted before 2001, petitioner relies on the general term "non-patient care activities" in Section 5505(b). Petitioner contends (Pet. 21-30) that "non-patient care activities" plainly includes pure research and that, because all "non-patient care activities" are to be included for the cost reporting periods at issue, so too are research activities. That is incorrect.

Petitioner first relies on what it asserts is the "ordinary meaning" (Pet. 25) of the term "non-patient care activities" to argue that pure research is necessarily a subset of non-patient care. But, as the court of appeals held (Pet. App. 6a-7a), that term is not self-defining. Rather than provide a statutory definition, Congress expressly granted authority to the Secretary to "define[]" what "time and activities" should be included in the FTE resident count. See ACA § 5505(b), 124 Stat. 661. The fact that Section 5505(b) authorizes the Secretary to define "non-patient care activities" demonstrates that Congress regarded it as a term of art, to be fleshed out by the Secretary in the exercise of her programmatic judgment. See Pet. App. 7a (observing that "[t]he

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[3] The understanding that Congress did not opine on the status of pure research time prior to 2001 was widely shared. Indeed, in commenting on the Secretary's proposed rule, the Association of American Medical Colleges (AAMC), of which petitioner is a member, itself acknowledged that ACA "does not opine on the status of IME research prior to October 1, 2001." Letter from Darrell G. Kirch, M.D., President & Chief Exec. Officer, AAMC, to Donald Berwick, M.D., Administrator, CMS at 10 (Aug. 31, 2010), https://www.aamc.org/download/150394/data/2011_opps_comments_dgme_ime.pdf.pdf; see 75 Fed. Reg. at 72,145 (discussing comment).

request to define implies a need to define"); *Women Involved in Farm Econ.* v. *United States Dep't of Agric.*, 876 F.2d 994, 1000 (D.C. Cir. 1989) ("Congress explicitly authorized the Secretary to define the term 'person,'" which "necessarily suggests that Congress did *not* intend the word to be applied in its plain meaning sense."), cert. denied, 493 U.S. 1019 (1990) .

Moreover, the structure of Section 5505 makes clear that Congress did not regard "non-patient care activities" as plainly including pure research. Throughout Section 5505, Congress consistently treated "research activities" as distinct from "didactic conferences and seminars." See ACA § 5505(a)(1)(B), 124 Stat. 660 (including "didactic conferences and seminars" but excluding "research" activities in FTE count for purposes of DGME adjustment). Section 5505(b) refers only to the former in Clause (x)(II), when it uses the term "non-patient care activities," and specifically addresses the latter in Clause (x)(III). Compare § 5505(b), 124 Stat. 660-661 (referencing only "didactic conferences and seminars"), with § 5505(b), 124 Stat. 661 (referencing only "research activities"). If Congress had intended to require the Secretary to include pure research for cost reporting periods before 2001, it would have said so expressly in the paragraph that specifically speaks to research activities—or, at the very least, it would have directly referred to research as a subset of "non-patient care activities" in the former paragraph.

Petitioner next contends (Pet. 21-25) that a comparison between Section 5505(a) and Section 5505(b) demonstrates that Congress intended pure research to be categorized as a "non-patient care activit[y]" for purposes of the IME adjustment. Petitioner misreads Section 5505(a). That provision addresses the DGME payment

for activities outside the hospital setting and provides that "all time spent by an intern or resident * * * in non-patient care activities, such as didactic conferences and seminars, but not including research not associated with the treatment or diagnosis of a particular patient, *as such time and activities are defined by the Secretary*," shall be included in the FTE resident count. ACA § 5505(a)(1)(B), 124 Stat. 660 (emphasis added). Section 5505(a) evidences Congress's recognition that the Secretary *could* reasonably define the term "non-patient care activities" to include "research not associated with the treatment or diagnosis of a particular patient." To eliminate the Secretary's discretion to define "such time and activities" to include pure research when calculating the DGME adjustment, Congress explicitly excluded such time from the FTE count. Congress made a different decision for the pre-2001 IME adjustment. As the court of appeals noted, "it is perfectly sensible * * * to specify that pure research is not reimbursable as a category of 'direct' costs [(incurred "outside the hospital")], but to allow the Secretary to make the call for 'indirect' costs [("incurred in the hospital")]." Pet. App. 10a.

Petitioner additionally argues that pure research must be a "*non*-patient care" activity because it is not a "patient care" activity. Pet. 26-29 (emphasis added). Relatedly, petitioner contends that the Secretary's authority was limited to deciding whether a particular activity qualifies as "non-patient care," as opposed to "patient care"—not to create a "third category" that is neither. Pet. 27-29. Whatever sense that may make in the abstract, it makes none in this statutory scheme. Under petitioner's interpretation, all "patient care" activities are included in the FTE resident count and all "non-patient care" activities are *also* included in the FTE

count. If Congress had meant to encompass the entire universe of activities by students in graduate medical education programs before 2001 (as either "patient care" or "non-patient care"), it would have had no reason to use the term "non-patient care activities" at all, much less to charge the Secretary with defining that term. Congress would have instead directed the Secretary to count *all* activities of medical residents. By expressly using the term "non-patient care activities" and by authorizing the Secretary to define that term, Congress necessarily recognized that some resident activities may not be included in the FTE count because they neither qualify as "patient care" or "non-patient care" for purposes of the IME adjustment.

The cases petitioner relies on (Pet. 26-27) are inapposite. In *USPS* v. *Postal Regulatory Commission*, 599 F.3d 705 (D.C. Cir. 2010), the court of appeals did not assume that the term "nonpostal service" was self-defining; the statute itself defined a "nonpostal service" as "any service that is not a postal service." *Id.* at 707 (citation and emphasis omitted). In *Zemon Concrete Corp.* v. *Occupational Safety & Health Review Commission*, 683 F.2d 176, 179 n.8 (7th Cir. 1982) (*Zemon*) (per curiam), the issue was whether a subcontractor had notice of the charges against it when the first citation was labeled "serious" and the second was labeled "other." Because the statute characterized all violations as either "serious" or "non-serious," the court concluded that the term "other" provided sufficient notice that the violations were "non-serious." *Ibid.* Moreover, in both cases, the two categories were subject to different treatment under the statutory scheme such that it was necessary to use the prefix "non" to distinguish between them. See *USPS*, 599 F.3d at 707 ("nonpostal services" were sub-

ject to review; "postal services" were not); *Zemon*, 683 F.2d at 177 n.1 ("serious" violations were subject to different penalty than "non-serious" violations).[4]

Finally, contrary to petitioner's contention (Pet. 16-18), the court of appeals did not improperly defer to the Secretary at the first step of the *Chevron* analysis. In arguing otherwise, petitioner relies on a single paragraph of the opinion where the court addressed the Seventh Circuit's decision in *University of Chicago Medical Center* v. *Sebelius*, 618 F.3d 739 (2010). That paragraph comes after a full discussion of the statutory text, structure, and context in which the court did not defer to (or even discuss) the Secretary's regulation. Pet. App. 6a-11a. Only after concluding that analysis did the court note some "tension" with the Seventh Circuit's decision and, in that context, state that the existence of the regulation "converted a run-of-the-mine statutory interpretation case into a *Chevron* case." *Id.* at 11a. Far from evidencing premature deference to the Secretary, the court simply recognized that before the Secretary promulgated her regulation, there was no authoritative administrative interpretation to which the Seventh Circuit could have deferred.

b. The court of appeals also correctly held that the Secretary "acted within her authority by excluding pure research from 'non-patient care activities, such as didac-

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[4] The court of appeals relied on the far more analogous case of *Wint* v. *Yeutter*, 902 F.2d 76 (D.C. Cir. 1990). See Pet. App. 8a. As petitioner observes, "[t]he D.C. Circuit found that the agency could permissibly exclude some crops from [the term] 'fruits and vegetables' because 'Congress could have said simply "all plants" if Congress had indeed meant just that.'" Pet. 29 (quoting *Wint*, 902 F.2d at 82). The same is true here. If Congress had meant to include all of a resident's activities in the FTE count (whether they qualified as "non-patient care" or "patient care"), it would have simply said all activities.

tic conferences and seminars.'" Pet. App. 12a; see *Chevron U.S.A. Inc.* v. *NRDC*, 467 U.S. 837, 843-844 (1984) (When Congress "express[ly] delegat[es] * * * authority to the agency to elucidate a specific provision of the statute by regulation," the agency's regulations are given "controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute."). Petitioner's arguments to the contrary (Pet. 30-35) are without merit.

Exercising her express authority to define "the time spent by an intern or resident * * * in non-patient care activities," the Secretary reasonably concluded that "research not associated with the treatment or diagnosis of a particular patient" should be treated differently than "non-patient care activities, such as didactic conferences and seminars." 75 Fed. Reg. at 72,145; see 42 C.F.R. 412.105(f)(1)(iii)(B) and (C). As the Secretary explained, from the very outset of the Medicare program, pure "research costs have not been considered reasonable costs of patient care." 75 Fed. Reg. at 72,144. Moreover, didactic conferences and seminars could benefit current Medicare patients by, for example, including "an administrative rotation" or involving "presentations or discussions related to the treatment of current patients." *Id.* at 72,144-72,146. Pure research, on the other hand, is by definition "not associated with the treatment or diagnosis of a particular patient." 42 C.F.R. 412.105(f)(1)(iii)(B). And whereas "interns and residents are often assigned to blocks of research time, * * * didactic conferences and seminars may occur * * * when an intern or resident is otherwise assigned to a rotation primarily requiring the provision of patient care." 75 Fed. Reg. at 72,145-72,146.

Petitioner contends (Pet. 30-33) that the Secretary's interpretation is unreasonable because it "impos[es] a patient care requirement on expressly non-patient care activities." That argument, however, rests on petitioner's faulty contention that all of a resident's activities consist of either "patient care" or "non-patient care." Once it is understood that a third category of activities may exist, and that some of a resident's activities may be excluded from the FTE count, the Secretary's "reasonabl[e] belie[f] that Medicare primarily focuses on patient care" becomes quite relevant, and the court of appeals correctly concluded that the Secretary could reasonably decide to "reimburse only those non-patient care activities that seem to benefit current patients." Pet. App. 12a.[5]

Petitioner also suggests that Congress would not have authorized the Secretary to define "non-patient care activities" to exclude "research that is not associated with the treatment or diagnosis of a particular patient," Pet. 33-35 (quoting 75 Fed. Reg. at 72,144), because, based on the Secretary's prior position, that out-

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[5] In noting that the district court rejected the Secretary's assertion that "Medicare reasonably focuses on patient care, not research," petitioner appears to suggest that the "the district court's holding" has some remaining force. Pet. 31-32. That is incorrect. The court of appeals reversed the district court based on intervening statutory and regulatory developments, and did not opine on the correctness of the district court's ruling. The only court of appeals to rule on the validity of the Secretary's interpretation of the pre-2001 regulation, however, held that the Secretary reasonably excluded pure research. See *Rhode Island Hosp.*, 548 F.3d at 43 (noting that "[e]ducational research expenses do not directly increase the costs teaching hospitals incur in providing patient care" and, "[a]s a result," declining to hold that "the Secretary's reading of the FTE regulation frustrates the policies Congress sought to implement").

come was preordained, *ibid.* Again, that rests on the erroneous assertion that Congress decided for itself that such research activities must be counted for cost reporting years prior to 2001. As discussed above, that is not what Section 5505 says.

Finally, petitioner argues (Pet. 34-35) that the Secretary has changed positions by treating pure research as a "non-patient care activity." The Secretary, however, has always maintained that pure research should be excluded from the IME adjustment because it is unrelated to the cost of patient care in teaching hospitals. The Secretary reasonably interpreted the pre-2001 regulation to adopt that position. See *Rhode Island Hosp.*, 548 F.3d at 34-44. And the Secretary made that interpretation explicit in 2001. See 42 C.F.R. 412.105(f)(1)(iii)(B) (2001). The reason the Secretary has consistently excluded pure research from the IME calculation is because "[s]uch activities are not related to the provision of patient care medical services for Medicare patients and, accordingly, should not be considered for the basis of calculating Medicare reimbursement." Pet. App. 68a. To be sure, Congress implicitly rejected the Secretary's rationale as applied to "non-patient care activities, *such as* didactic conferences and seminars." ACA § 5505(b), 124 Stat. 661 (emphasis added). But Congress otherwise left intact the Secretary's authority to define the "time and activities" that should be counted as part of the IME adjustment. The Secretary appropriately exercised that authority consistent with the agency's prior practice.

2. Three courts of appeals have decided whether a resident's pure research time should be included in the hospital's FTE resident count for IME purposes for cost reporting periods before 2001, but they have each done

so under a different statutory and regulatory regime. There is no square conflict and any disagreement among the courts of appeals is shallow and is of limited prospective importance.

The First Circuit was the first court of appeals to consider whether the Secretary had reasonably excluded time spent on pure research in calculating a hospital's IME adjustment for cost reporting periods prior to 2001. See *Rhode Island Hosp.*, *supra*. The issue in that case was whether residents assigned to perform research activities not associated with the treatment or diagnosis of a particular patient were "assigned" to an "area" or "portion of the hospital subject to the prospective payment system," under the Secretary's then-governing regulation. 548 F.3d at 34 (citation omitted). The court ultimately concluded that the regulation was ambiguous and that the Secretary's interpretation of that regulation (excluding time spent on pure research) was reasonable and consistent with the statutory scheme. *Id.* at 35-44.[6]

The Seventh Circuit also considered whether pure research should be included when calculating a hospital's pre-2001 IME adjustment, but that court relied on the intervening statutory amendment in Section 5505 of ACA to decide the question. See *University of Chi.*

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[6] Petitioner cites (Pet. 5, 32) five district court opinions that reached a contrary conclusion. Three of those decisions were appealed, and none was affirmed on that ground. See Pet. App. 1a-14a (reversing district court based on intervening statute and regulation); *University of Chi. Med. Ctr., supra* (affirming district court based on intervening statute); *Rhode Island Hosp.*, *supra* (reversing district court). *Riverside Methodist Hosp.* v. *Thompson*, No. C2-02-94, 2003 WL 22658129 (S.D. Ohio July 31, 2003), was unpublished, was not ultimately appealed, and did not involve pure research. *University Med. Ctr. Corp.*, *supra*, was unpublished and was not ultimately appealed.

Med. Ctr., *supra*. The Seventh Circuit determined that it did not need to resolve the parties' dispute about the pre-2001 regulation because Section 5505 was "dispositive." 618 F.3d at 744, 745-746. Turning to that section, the court considered whether "non-patient care activities" include "research activities that are not associated with the treatment or diagnosis of a particular patient." *Id.* at 745. The court concluded that the hospital had the "stronger position" and that Congress "spoke clearly when it retroactively allowed reimbursement for non-patient care activities starting in 1983." *Ibid.* Relying on "ordinary parlance" and "the amendments to the DGME reimbursement," the court also determined that "research activities" are a "subset of non-patient care activities." *Ibid.* Finally, the court observed that while its position was "contrary to the First Circuit's opinion, * * * the First Circuit did not have the opportunity to consider Congress's health care legislation." *Id.* at 745-746.

Here, the court of appeals decided the same question, but under yet another regime. The Secretary issued her final rule implementing Section 5505 of ACA after the Seventh Circuit's decision and while this case was pending on appeal. Although the court of appeals correctly noted some "tension" (Pet. App. 11a) between its decision and *University of Chicago Medical Center*, when the Seventh Circuit considered the issue, it did not discuss the significance of the fact that "the statute expressly delegates to the Secretary the authority to 'define[]' eligible 'non-patient care activities.'" *Id.* at 7a (brackets in original) (quoting ACA § 5505(b), 124 Stat. 661). At that time, the Secretary had not exercised her authority and the court made no mention of the statutory delegation. Thus, when the Seventh Circuit relied

on "ordinary parlance" to define "non-patient care activities" to include research activities, *University of Chi. Med. Ctr.*, 618 F.3d at 745, it did not take into account the fact that Congress assigned that definitional task to the Secretary, which alone indicates that the statutory text itself does not answer the question. And, as the court below noted (Pet. App. 11a), at the time of the Seventh Circuit's decision, the Secretary had not *exercised* that authority, which underscores the significance of that express delegation in the overall statutory context.[7]

Any conflict between the two court of appeals' decisions is, in any event, shallow and review is not warranted. The court of appeals below is the only court to have considered how pure research should be treated for purposes of the pre-2001 IME calculation under the current statutory and regulatory regime. The Seventh Circuit may have an opportunity to reconsider its decision in light of Congress's express grant of authority to the Secretary and the Secretary's exercise of that authority in the final rule.[8] To the extent other courts of appeals

[7] Petitioner notes (Pet. 19) that the Seventh Circuit later denied the Secretary's motion for panel rehearing. When the Secretary moved for rehearing, however, she had only proposed a rule and submitted it for notice and comment. See 75 Fed. Reg. at 46,170, 46,387-46,389, 46,464. There was no final regulation warranting *Chevron* deference. The final rule was published in the *Federal Register* after the panel's order denying rehearing. See Order Denying Rehearing, *University of Chi. Med. Ctr.*, No. 09-3429 (Nov. 3, 2010); 75 Fed. Reg. at 71,800 (Nov. 24, 2010).

[8] In appeals involving a hospital located in the Seventh Circuit, the PRRB recently adopted the reasoning of the court of appeals in this case. See *Rush Univ. Med. Ctr.*, Nos. 96-0819 & 97-1814, 2012 WL 983159, at *8-*9 (Feb. 8, 2012); *Rush Univ. Med. Ctr.*, No. 00-2351, 2012 WL 983160, at *9-*10 (Feb. 8, 2012). The Administrator of CMS, acting on behalf of the Secretary, affirmed the Board's decisions in two separate decisions issued on April 4, 2012.

may ultimately consider that same issue (see Pet. 21), further development in the lower courts should precede this Court's review.

Review by this Court is also unwarranted because any current (or predicted future) disagreement among the courts of appeals is of limited prospective importance. The question presented affects only cost reporting periods before October 1, 2001. See ACA § 5505(b) and (c)(3), 124 Stat. 660-661. And it affects only those cost reporting periods for which an IME resident count was still being reviewed or audited, or was at issue in a pending appeal, as of March 23, 2010. See § 5505(d) (as added by ACA § 10501(j)), 124 Stat. 999; 75 Fed. Reg. at 72,142. As petitioner notes (Pet. 20), there are two additional cases pending in federal court. The Department of Health and Human Services has also informed us that there are approximately a dozen hospitals located outside the Sixth and Seventh Circuits with appeals pending before the PRRB. This is largely a fixed and closed set of cases. For that reason as well, further review is not warranted.[9]

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[9] The constitutionality of the minimum coverage provision of ACA, and the severability of that provision from other provisions of the Act, are before the Court in *Department of Health and Human Services* v. *Florida*, No. 11-398, *National Federation of Independent Business* v. *Sebelius*, No. 11-393, and *Florida* v. *Department of Health and Human Services*, No. 11-400 (argued Mar. 27 and 28, 2012). The Sixth Circuit's decision in this case is cited in the government's severability brief (at 31 n.14) in Nos. 11-393 and 11-400.

Petitioner does not challenge the constitutionality of the minimum coverage provision of the Act or contend that Section 5505 of ACA should be held inseverable and invalid on that ground if the minimum coverage provision were held unconstitutional. Nor does petitioner suggest that this case be held pending the Court's decision in those cases or advert to their pendency in this Court. There accordingly is no reason to hold the petition in this case pending the Court's decision in

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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Department of Health and Human Services v. *Florida*, and the related cases.