IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 16-50398

United States Court of Appeals
Fifth Circuit
FILED
June 22, 2017
Lyle W. Cayce
Clerk

MAXMED HEALTHCARE, INCORPORATED,

Plaintiff - Appellant

v.

THOMAS PRICE, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendant - Appellee

Appeal from the United States District Court
for the Western District of Texas

Before JONES and OWEN, Circuit Judges, and ENGELHARDT, District Judge*.

EDITH H. JONES, Circuit Judge:

The Secretary of Health and Human Services determined that the Medicare program overpaid plaintiff-appellant Maxmed Healthcare, Inc., by almost $800,000 for home health care services rendered to Medicare beneficiaries. Maxmed sought judicial review, arguing principally that the overpayment calculation was in error to the extent it extrapolated from a group of noncompensable services to estimate an overpayment three times larger.

* Chief Judge of the Eastern District of Louisiana sitting by designation.

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The district court granted summary judgment to the Secretary and denied Maxmed's motion to amend or alter the judgment. We **AFFIRM**.

BACKGROUND

The Medicare program reimburses health care providers who render services to Medicare beneficiaries. Congress created the Medicare Integrity Program through which the Secretary contracts with private entities "for the purpose of identifying underpayments and overpayments and recouping overpayments[.]" *See* 42 U.S.C. § 1395ddd(a), (h)(1).

Extrapolation is one permissible method of calculating overpayments. In particular, Congress authorized Medicare contractors to "use extrapolation to determine overpayment amounts" if the Secretary determines that "there is a sustained or high level of payment error." *Id.* § 1395ddd(f)(3)(A).

The Centers for Medicare and Medicaid Services (CMS), the agency responsible for administering Medicare, has issued two key documents that govern the use of extrapolation. One document, Ruling 86-1, provides that sampling for extrapolation purposes "only creates a presumption of validity as to the amount of an overpayment which may be used as the basis for recoupment." Following an overpayment determination based on extrapolation, the burden shifts to the Medicare provider, who "could attack the statistical validity of the sample, or [] could challenge the correctness of the determination in specific cases identified by the sample[.]" The second document is the Medicare Program Integrity Manual, which sets out "[t]he major steps in conducting statistical sampling," and articulates a number of criteria that govern the specifics of each step in the extrapolation process. *See* Medicare Program Integrity Manual (MPIM) § 8.4.1.3; *see also id.* §§ 8.4.3.1

(Period for Review), 8.4.3.2.1 (Composition of the Universe), 8.4.3.2.2 (Sample Unit), 8.4.4.3 (Sample Size).[1]

Providers who dispute an overpayment determination may challenge it in a lengthy appeal process. At the outset, a Medicare Administrative Contractor makes an "initial determination" regarding the overpayment amount. *See* 42 C.F.R. § 405.920. A provider who is displeased with the Medicare Administrative Contractor's initial determination may then seek a "redetermination"—the first step in a five-step appeal process. *Id.* §§ 405.940–.958. The redetermination is conducted by employees of the Medicare Administrative Contractor who were not involved in the initial determination. *Id.* § 405.948. Second, if the provider remains dissatisfied, the provider may request a "reconsideration." *Id.* § 405.960. A Qualified Independent Contractor, another private contractor, conducts the "independent" reconsideration. *Id.* § 405.968. Third, if the provider still remains dissatisfied, the provider may request a hearing before an administrative law judge (ALJ). *Id.* § 405.1000(a). The ALJ reviews the case *de novo*. *Id.* § 405.1000(d). Fourth, either the provider or CMS, through its contractors, may request that the Medicare Appeals Council (Council) review the ALJ's decision. *Id.* § 405.1100(a). The Council, like the ALJ, reviews the case *de novo*, and its decision constitutes the Secretary's final decision. *Id.* § 405.1000(c). Fifth, if all else fails, the provider is entitled to "judicial review of the Secretary's final decision . . . as is provided in section 405(g) of this title." 42 U.S.C. § 1395ff(b)(1)(A).

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[1] A copy of MPIM Chapter 8 may be found at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c08.pdf (last visited June 20, 2017). At the time of the agency proceedings in this case, the relevant MPIM provisions were located in Chapter 3. Subsequently, the provisions were relocated to Chapter 8, and both parties assure us that the provisions are substantively unchanged.

Over the past six years, Maxmed navigated the appeal process from start to finish. Maxmed is a home health agency that provided home health services to Medicare beneficiaries. Maxmed submitted claims for services to its Medicare Administrative Contractor, Palmetto GBA, and received payments accordingly. In 2011, however, Palmetto GBA informed Maxmed that it calculated overpayments between April 2008 and March 2010. Palmetto GBA explained that Health Integrity, LLC, a private contractor charged with investigating potential overpayments, determined that Maxmed had been "overpaid in the amount of $773,967.00." Health Integrity reviewed a sample of 40 claims, submitted on behalf of 22 beneficiaries during that period, and determined all but one noncompensable either because the patients were not homebound or the services provided were not medically necessary. *See* 42 U.S.C. § 1395f(a)(2)(C) (requiring a physician's certification that "in the case of home health services, such services are or were required because the individual is or was confined to his home . . . and needs or needed skilled nursing care"). This was an "error" rate exceeding 97%. The overpayment amount attributable to the disapproved claims was $264,584.51. Health Integrity then statistically extrapolated to a universe of 130 claims, which yielded a total overpayment amount of $773,967. Palmetto GBA instructed Maxmed to repay the larger amount.

Maxmed invoked the five-step appeal process to challenge the overpayment determination. Maxmed challenged both the denial of coverage for the claims and the extrapolation to 130 overpayments. Maxmed lost at the redetermination and reconsideration levels before prevailing after an ALJ hearing.

In a 106-page ruling, the ALJ thoroughly examined each of the cases of the 22 beneficiaries and found nearly all of their claims noncompensable or overpaid. She ruled in favor of Maxmed on only one of the individual claims.

The ALJ then took up multiple challenges to Health Integrity's statistical sampling methodology and relied heavily on a report by an independent statistician, not retained by Maxmed, who disagreed with the overpayment calculations. Ultimately, the ALJ found that Health Integrity's extrapolation methodology was fatally flawed in a number of ways, including (1) the failure to record the random numbers used in the sample as required by the MPIM; (2) the failure to properly define sampling units; (3) the failure to demonstrate the sampling units' independence; and (4) the failure to demonstrate average overpayment was normally distributed. The ALJ invalidated the extrapolation methodology and the overpayment amounts based on the methodology.

CMS referred the ALJ's decision to the Council, as it is entitled to do, seeking "own-motion" review. The Council, ruling *de novo*, affirmed the ALJ's assessment that the 22 beneficiaries' individual cases were (with one exception) not eligible for Medicare coverage, but reversed the ALJ's determinations about extrapolation and sampling. Like the ALJ, the Council noted that an appeal challenging the validity of the sampling methodology must be predicated on the actual statistical validity of the sample as drawn and conducted. *See* MPIM § 8.4.1.1. Further, like the ALJ, the Council noted Maxmed's burden was to overcome the presumption of validity of the sampling and extrapolation methodology. CMS Ruling 86-1. The Council concluded that the ALJ "erred as a matter of law in her application of CMS Ruling 86-1 and MPIM guidance and erred as a matter of fact by concluding that the evidence of record establishes that the statistical sampling and extrapolation were invalid." The Council addressed numerous generic and specific challenges to Health Integrity's sampling and extrapolation methodology. Pertinent to this appeal, the Council held that "the MPIM does not require that the list of random numbers be provided," because the sample selected by Health Integrity could be replicated by other means. Further, the Council rejected

Maxmed's contention that the sampling units were not independent because (1) the record did not prove this assertion; (2) multiple claims pertaining to individual beneficiaries were "independent" because they were generated in separate 60-day increments; and (3) the MPIM expressly contemplates the use of "claims, individual claims, or clusters of claims (e.g. a beneficiary)" as the sampling units. MPIM, ch. 3, §3.10.3.2.2.[2] Finally, finding no authority for Maxmed's "sweeping proposition," the Council summarily rejected Maxmed's "additional" argument that extrapolation violates the agency's "Rule of Thumb," which, according to Maxmed, requires individualized review of each beneficiary's medical record.

Maxmed sought judicial review of the Council's decision. The company no longer challenges its liability to repay over $250,000 based on services that were found not medically reasonable and necessary, nor does it raise many of the technical issues concerning extrapolation that were covered in its briefing before the ALJ and the Council. In federal court, Maxmed raised various issues challenging the Council's decision and contended that it was deprived of due process because it was denied timely, critical information about the extrapolation methodology. The district court granted summary judgment to the Secretary. The court affirmed the Council's resolution of the extrapolation issues for essentially the same reasons invoked by the Council. The court found no due process violation because Maxmed had an "encrypted CD [with] an explanation and details of the findings" for the entire duration of the appeal process, and Maxmed had all relevant information at least "prior to the hearing before the ALJ."

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[2] The concept of "independence" is important to a proper extrapolation. As the ALJ stated, "[t]he concept of independence means that the (a) probability of denying the payments from one sampling unit does not affect (b) the probability of denying the payments to any other sampling unit in the frame. This form of independence is completely separate from the random selection of sampling units from the frame."

Maxmed moved to amend or alter the judgment, attaching four complaints in different lawsuits filed by Maxmed's counsel that were presented as "new evidence" demonstrating arbitrary extrapolation. The district court denied the motion because "the[] complaints [did] not adequately inform the Court as to the parties' evidence, records, testimony, and statistical sampling, and whether they are exactly the same as those at issue in this case."

Now, six years after the Secretary first demanded repayments, Maxmed appeals the district court's grant of summary judgment and denial of the motion to amend or alter the judgment.

STANDARD OF REVIEW

Because Maxmed raises a variety of claims, the standard of review varies from claim to claim. First, as to the validity of the overpayment methodology on which the district court granted summary judgment, "[t]his court reviews a grant of summary judgment *de novo*, applying the same standard to review the agency's decision that the district court used." *Baylor Cty. Hosp. Dist. v. Price*, 850 F.3d 257, 261 (5th Cir. 2017). The Secretary contends that the appropriate standard is confined to 42 U.S.C. §405(g): "(1) whether the [Secretary] applied the proper legal standards; and (2) whether the [Secretary's] decision is supported by substantial evidence on the record as a whole." *See Estate of Morris v. Shalala*, 207 F.3d 744, 745 (5th Cir. 2000). Maxmed argues that this court should consider, under the Administrative Procedure Act, whether the Secretary's decision is not founded on substantial evidence or is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *See* 5 U.S.C. § 706(2)(A), (E). This court recently addressed the same debate between a medical services provider and CMS and "assume[d] only for the sake of argument that the APA's arbitrary and capricious standard applies." *Baylor Cty. Hosp. Dist.*, 850 F.3d at 261. Because the standard of review "probably makes no difference," *id.*, we make the same assumption here, too.

Second, this court reviews the denial Maxmed's motion to alter or amend the judgment under Fed. R. Civ. P. 59(e) for abuse of discretion. *See Rosenblatt v. United Way of Greater Hous.*, 607 F.3d 413, 419 (5th Cir. 2010). "[A] motion to alter or amend the judgment under Rule 59(e) 'must clearly establish either a manifest error of law or fact or must present newly discovered evidence' and 'cannot be used to raise arguments which could, and should, have been made before the judgment issued.'" *Id.* (quoting *Rosenzweig v. Azurix Corp.*, 332 F.3d 854, 864 (5th Cir. 2003) (quoting *Simon v. United States*, 891 F.2d 1154, 1159 (5th Cir. 1990))) (alteration in original).

Finally, this court reviews the grant of summary judgment against Maxmed's due process claim *de novo*. Summary judgment is proper "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." *See, e.g.*, *Rogers v. Bromac Title Servs., L.L.C.*, 755 F.3d 347, 350 (5th Cir. 2014) (quoting Fed. R. Civ. P. 56(a)).

DISCUSSION

Maxmed argues that substantial evidence does not support the Council's decision to approve the integrity contractors' sampling and extrapolation methodology and the Council's decision was arbitrary and capricious. To this end, the company focuses on the arguments highlighted above—random numbers should have been recorded, the sampling units were not independent, the Rule of Thumb prohibits extrapolation, and the four lawsuit complaints highlighted in its post-judgment motion illustrate arbitrary extrapolation. Maxmed also asserts that its due process rights were violated. None of these arguments has merit.

I. Random Numbers

Maxmed contends that the extrapolation is invalid because the Secretary, acting through its contractors, failed to document the random

numbers used in the sample and how they were selected. Maxmed relies on MPIM section 8.4.4.4.1, which states that

> [a] record shall be kept of the random numbers actually used in the sample and how they were selected. Sufficient documentation shall be kept so that the sampling frame can be re-created, should the methodology be challenged.

The Secretary does not dispute that there is no record of the random numbers in this case.

But, as the Secretary notes, this fact does not necessarily invalidate the extrapolation methodology, at least under the MPIM. Note that the quoted section refers also to "sufficient documentation . . . so that the sampling frame can be re-created." Maxmed does not argue that the failure to record the random numbers actually rendered the sampling invalid, and it ignores the stated goal of maintaining the random numbers. Health Integrity's chief statistician was able to replicate the sample of 40 claims using the information available to Maxmed.

Moreover, MPIM section 8.4.1.1 makes clear that a contractor's failure "to follow one or more of the requirements contained herein does not necessarily affect the validity of the statistical sampling that was conducted or the projection of the overpayment." Instead, "[a]n appeal challenging the validity of the sampling methodology must be predicated on the actual statistical validity of the sample as drawn and conducted." MPIM § 8.4.1.1. Section 8.4.1.1 concludes by reemphasizing that a contractor's failure to follow all MPIM requirements "should not be construed as necessarily affecting the validity of the statistical sampling and/or the projection of the overpayment." Maxmed's argument is inconsistent with the MPIM, and the Secretary did not arbitrarily reject this argument.

II. Sampling Units' Independence

Maxmed also argues that the MPIM requires the Secretary's contractors, to "obtain a statistically valid random sample of processed Medicare claims that are defined correctly and independent." Maxmed contends that the sampling in this case was fatally *dependent* because the same Medicare beneficiary could have multiple claims or claim lines in the sample. The independent expert Dr. Haller found, and the ALJ agreed, that using multiple claims for one beneficiary in the sample rendered the sampling units not independent. MPIM section 8.4.10, entitled "Resources," lists authoritative texts on statistical methods, several of them referenced in Dr. Haller's opinion, which explain the proper concepts used by academics.

As explained by the Council, however, the MPIM does not actually have a strict "independence" requirement that conforms to authoritative statistical standards and texts. The Council criticized Dr. Haller's "assertion that confidence interval extrapolation requires the sampling units to be wholly independent," and found that it "represents another example of [his] effort to incorporate by reference academic standards that are not contemplated in CMS guidance or consistent with real-world Medicare practices."

Moreover, the MPIM expressly permits a sample to include multiple claims or claim lines from the same beneficiary. Section 8.4.3.2.2 provides that sampling units "may be an individual line(s) within claims, individual claims, or clusters of claims (e.g., a beneficiary)." Not only that, but the Council was not persuaded that the sample units were in fact dependent. The Council credited Health Integrity's statistician, who testified that because different dates of service are covered by each claim, the fact that a single beneficiary was involved did not compel the same medical review result for each claim. And although Dr. Haller characterized the sample units as dependent, Maxmed's retained expert said he lacked sufficient information to determine

whether the sampling units are dependent or independent. Finally, Maxmed bore the burden but did not elect to challenge the compensability of any of the claims or claim lines used in the sampling units.

The conclusion of the Council's reasoning in rejecting Maxmed's challenge to the sampling and extrapolation methodology is worth repeating:

> Suffice it to say, given MPIM provisions, the fact that [Health Integrity] selected a sampling methodology or sample size that another statistician may not prefer, or which may not result in the most precise point estimate, does not provide a basis for invalidating the sampling or the extrapolation as drawn and conducted in this case. . . . The Council must give substantial deference to CMS guidelines including where, as here, CMS has chosen a reasonable, feasible, and well-articulated approach for collecting overpayments which, by design, offsets precision in favor of lower recovery amounts. To the extent that [Dr. Haller] or other statisticians have significant concerns with the parameters of CMS's statistical sampling guidelines, those concerns should be raised with CMS, as the Council has no authority to invalidate CMS guidelines.

To be sure, Maxmed may have had a viable argument that the only reasonable interpretation of the statutory term "extrapolation" includes "independence" as understood by statisticians who have developed and articulated the governing concepts. Such an interpretation could place the Secretary's non-technical interpretation outside the range of permissible interpretations under *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). Maxmed does not make this argument but relies instead on the MPIM, and there is no basis for its MPIM argument. The Secretary did not act arbitrarily and capriciously in rejecting the challenge to the independence of the sampling units.

III. Rule of Thumb

CMS's Medicare Benefit Policy Manual (MBPM) provides that a "determination of whether home health services are reasonable and necessary

must be based on an assessment of each beneficiary's individual care needs." MBPM Chap. 7, § 20.3.[3] The parties refer to this provision as a "Rule of Thumb." Maxmed contends that the use of extrapolation violates the Rule of Thumb because extrapolation is not based on an assessment of each beneficiary's *individual* care needs. The upshot of this argument is that any overpayment should only be determined after a review of each beneficiary's specific claims, and it is fundamentally at odds with extrapolation concerning home health care claims. The Council rejected the argument because Maxmed "point[ed] to no authority for such a sweeping proposition." The district court affirmed for the same reason and also because Maxmed did not suggest "any alternative means to calculate the overpayment in this case that would not violate the 'Rule of Thumb.'"

We agree with the Council and the district court. Maxmed's contention contradicts the statutory scheme. The Rule of Thumb makes sense for and applies to the prepayment review of individual coverage claims under Medicare. The MBPM provides guidance to Medicare contractors providing such prepayment review. What is appropriate when services are being authorized to Medicare beneficiaries, however, is not the standard for post-payment audits of providers. Congress authorized the Secretary's contractors to use extrapolation where, as in this case, "there is a sustained or high level of payment error[.]" 42 U.S.C. § 1395ddd(f)(3)(A). This provision is part of the overall fiscal integrity program governing "[r]eview of activities of providers of services or other individuals or entities furnishing items and services for which payment may be made under this subchapter (including skilled nursing facilities *and home health agencies*)[.]" 42 U.S.C. § 1395ddd(b)(1) (emphasis

[3] A copy of MBPM Chapter 7 is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c07.pdf (last visited June 20, 2017).

added). Thus, Congress clearly envisioned extrapolation in overpayment determinations involving home health agencies like Maxmed, and the Secretary's reliance on extrapolation as a tool was justified.

IV. Relevance of Similar Cases

Maxmed states that "[d]uring the course of judicial review, Maxmed learned of four similar administrative cases" in which the use of the same sampling methodology was rejected at the first stage of administrative review. Maxmed contends that the difference in results between those cases and the instant case shows that extrapolations and sampling are performed in an arbitrary, inconsistent manner. Discovery of this "new" evidence led Maxmed to ask the district court to amend or alter its decision pursuant to Rule 59(e), but the district court denied relief.

The court did not abuse its discretion. As the district court observed, all of the unverified complaints were filed by Maxmed's counsel while the summary judgment motion was pending. Yet more than a month after the district court rendered its decision, Maxmed asserted to the court that it had "newly discovered evidence" that "by due diligence could not have been discovered ahead of the decision." Such assertion is factually inconsistent with the filing dates of the four lawsuits. Predicating the denial of Maxmed's motion on that ground alone would not have been an abuse of discretion.

Moreover, Maxmed ignores the district court's statement that the "complaints do not adequately inform the Court as to the parties' evidence, records, testimony, and statistical sampling, and whether they are exactly the same as those at issue in this case." That statement is significant and correct: the complaints that Maxmed attached as exhibits to its motion do not contain details of the methodologies and other evidence at issue in those cases. For this additional reason the district court did not abuse its discretion in denying Maxmed's motion to amend or alter the judgment.

V. Due Process

Maxmed asserts that CMS and its contractors "deprived Maxmed of a meaningful opportunity to dispute and contest the overpayment by withholding critical evidence such as the statistical sampling and extrapolation data and information." Maxmed concedes that it obtained all of this information at least shortly before the ALJ hearing, and the Secretary disputes the untimeliness. Moreover, the information was thoroughly tested before the ALJ and the Council. The company nevertheless complains that the information was "withheld for years and through two appeal stages" (presumably referring to the redetermination and reconsideration stages).

We are unaware of any authority holding that agency processes become fundamentally unfair under the circumstances before us, where Maxmed never denies having received the information before the ALJ conducted a *de novo* hearing. The only case that Maxmed cites is inapposite. *See Chaves Cty. Home Health Serv., Inc. v. Sullivan*, 931 F.2d 914, 922–23 (D.C. Cir. 1991). No doubt, 42 U.S.C. § 1395ddd(f)(3) and 42 C.F.R. § 405.371 require the Secretary "to disclose information about the review and statistical sampling that was followed to calculate an overpayment[.]" It is unclear whether Maxmed requested this detailed information earlier in the administrative process, and Maxmed alleges in only conclusory terms that it was prejudiced by late disclosure. The district court properly rejected this claim.

* * *

We close with a note about how Maxmed's appeal fits within the larger pressing concerns surrounding Medicare appeals. Hundreds of thousands of Medicare appeals are backlogged in agency proceedings. After being prompted by the D.C. Circuit in *American Hospital Association v. Burwell*, 812 F.3d 183 (D.C. Cir. 2016), a district judge issued mandamus relief ordering the

Secretary to resolve the backlog by 2020 and adjudicate the appeals within statutorily imposed deadlines. *See Am. Hosp. Ass'n v. Burwell*, No. 14-851, 2016 WL 7076983 (D.D.C. Dec. 5, 2016) (mem. op.). In March 2017, the Secretary filed a status report in that case, indicating that the backlog is increasing, not decreasing, and that the Secretary "has no means to, and therefore cannot, meet the reduction targets . . . and simultaneously comply with the statutory requirements for appropriate payment of claims." Cochran Decl. at 4 (Mar. 6, 2017), ECF No. 55. In a second status report filed in June 2017, the Secretary reported that there are 607,402 pending appeals, and the Secretary projects that, absent legislative and budgetary measures, there will be nearly 1 million pending appeals by the end of Fiscal Year 2021. Defendant's Status Report at 2–3 (June 5, 2017), ECF No. 56. It appears that the Secretary awaits resources and funding from Congress to remedy the problem.

The practical realities are troubling. Providers like Maxmed who can afford to challenge overpayment determinations are mired in years of review (now six years for Maxmed). For many others who lack the necessary will or resources, such challenges are undoubtedly cost-prohibitive, and capitulation, even for meritorious objections, presents a more attractive option.

The problems don't end there. Think about the potential problems with extrapolation methodologies employed by private contractors who are awarded bounties for finding purported overpayments and whose findings are presumed valid.[4] Consider also the effect of multiple tiers of *de novo* agency review,

[4] See *Recovery Auditing in Medicare Fee-For-Service for Fiscal Year 2015*, Centers for Medicare & Medicaid Services vi, 4 (explaining that Recovery Audit Contractors—who work with the Medicare Administrative Contractors, Zone Program Integrity Contractors, and Qualified Independent Contractors—"are paid on a contingency fee basis," and the fees range from 9% to 17.5% of the overpayment amount), https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-

which render non-Council decisions and proceedings all but useless. Finally, if a provider endures until judicial review, the courts' highly deferential standards of review offer the vast majority of providers little hope of success.

Are these redundant, time-consuming, and costly procedures worthwhile for program integrity or providers? One is reminded of Prof. Gilmore's aphorism: "In Hell there will be due process, and it will be meticulously observed." Grant Gilmore, The Ages of American Law 111 (Yale 1977).

* * *

For the foregoing reasons, the district court's grant of summary judgment and denial of the motion to amend or alter the judgment are **AFFIRMED**.

Audit-Program/Downloads/FY2015-Medicare-FFS-RAC-Report-to-Congress.pdf (last visited June 20, 2017).