Report on
MEDICARE COMPLIANCE

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Weekly News and Compliance Strategies on Federal Regulations, Enforcement Actions and Audits

Contents

Rulings: Sampling, Extrapolations Should Include Underpayments, Unpaid Claims

In recent developments that could potentially affect overpayment findings, an administrative law judge (ALJ) invalidated a Medicare auditor's statistical sampling method because it removed underpayments, and the chief statistician for a Medicare administrative contractor (MAC) came to a similar conclusion in an unrelated appeal. If their point of view catches on, extrapolated overpayment amounts may be smaller in some cases, experts say.

The ALJ agreed with the appellant, a durable medical equipment (DME) supplier, that failing to include unpaid and underpaid service lines violated the *Medicare Program Integrity Manual*,[1] according to a June 18 decision. While it sounds technical, the ruling sends a message that Medicare auditors should consider both underpayments and unpaid claims in the extraction and extrapolation of audit samples, said attorney Stephen Bittinger, who represented the appellant. "This is a very important opinion," said Bittinger, with K&L Gates in Charleston, South Carolina. Leaving out unpaid claims, which have a dollar value of zero, and underpaid claims could "significantly skew" the audit at the starting gate. Other ALJs recently have come to the same conclusion in hearings, he noted.

Statistician/auditor Bruce Truitt, a former faculty member of the Medicaid Integrity Institute in Columbia, South Carolina, said he has been wondering for decades when a case like this would be won. "In a nutshell, all overpayments are improper payments, but not all improper payments are overpayments. Some are underpayments," he explained. "If you don't include underpayments, you never get to the correct value of the claim. As a result, the true dollar value, and conceivably the claim count of the universe, is not properly determined."

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Ohio Health System Settles Whistleblower Case for $21M; New Owner Also Self-Disclosed

Akron General Health System (AGHS) in Ohio will pay $21.25 million to settle false claims allegations that some physicians were paid very generously in exchange for patient referrals in a case involving both a whistleblower and a self-disclosure, the Department of Justice (DOJ) said July 2.[1] Beverly Brouse, the former interim compliance officer and director of internal audit at AGHS, allegedly brought her concerns about physician compensation to board members and executives but was rebuffed. Eventually she was fired and filed a False Claims Act (FCA) lawsuit Dec. 30, 2015. Around the same time, AGHS was acquired by the Cleveland Clinic Foundation, which self-disclosed noncompliant physician compensation arrangements at AGHS to DOJ about four months later.

According to the settlement,[2] DOJ alleged that between Aug. 1, 2010, and March 30, 2016, AGHS submitted claims to Medicare that violated the Anti-Kickback Statute (AKS) because it paid certain physicians compensation above fair market value to

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induce their referrals and violated the Stark Law because the compensation exceeded fair market value and/or took into account the volume or value of their referrals.

The FCA case was settled for single damages, which is unusually low for a false claims case, according to Warner Mendenhall, the whistleblower's attorney.

"This is a great example of the value of having an effective compliance program and a senior management team that walks the talk on doing the right thing," said Donald Sinko, chief integrity officer at Cleveland Clinic. "The noncompliance by Akron General was all prior to our acquisition, and our compliance program uncovered the problem right after we acquired them. As a result of our work, no actions were taken by the Justice Department against Cleveland Clinic." Sinko said Cleveland Clinic was unaware of the whistleblower complaint at the time of the self-disclosure.

Brouse worked in the AGHS compliance department for 10 years and in internal audit for two years. According to her complaint,[3] AGHS "initiated an aggressive strategy to increase its control over health care delivery around its hospital location" partly by buying physician practices and/or employing physicians to control their patient referrals. The employed physicians and physicians in personal service arrangements were paid excessive compensation "to ensure their substantial referral stream," the complaint alleged.

Every physician employed by AGHS was treated as a cost center, with billing and expenses attributed to the cost center. AGHS generally lost big sums of money year after year on its hospital-owned physician practices, but made up for it in their patient referrals to hospital services, the complaint alleged. To nail this calculation down, AGHS tracked the "contribution margin" of every physician, which is the revenue generated by the cost center for their hospital employer's inpatient services or outpatient ancillary services. "Controlling and capturing such referrals allows AGHS to ensure that its employed physicians are generating enough inpatient and ancillary service income to the hospital to more than make up for the losses on the excessive outpatient compensation," the complaint alleged.

For example, in June 2010, Akron General Medical Center (which was part of AGHS) bought the Center for Urologic Health (CUH) and entered into a five-year lease with the urologist employees, according to the complaint. The compensation included $7.2 million in annual base compensation for 12 physicians; a $553,846 signing bonus; and an incentive bonus of 9% of net collections for all professional fees billed by the medical center on behalf of the physicians, which turned out to be $1.56 million in 2013.

The average compensation for the CUH physicians after the medical center's acquisition was $680,769 in 2012 and $776,362 in 2013, the complaint alleged. By comparison, the median compensation paid nationally to hospital-employed urologists in 2012 was $192,000 and in 2014 was $328,000.

In November 2011, AGHS bought the assets of Internal Medicine of Akron Inc. (IMA) and entered into a professional and administrative services lease agreement with IMA for physician and related administrative services. Every year, the health system paid IMA $950,000 in base compensation for three physicians; an incentive bonus of 7.5% of net collections for their professional fees; and $80,000 for managing the practice. The incentive bonus added up to $157,639 in 2013. The average compensation that AGHS paid the IMA's three doctors was $369,213 in 2013, the complaint alleged. By comparison, the median compensation nationally for hospital-employed internists was $190,000 in 2014. The complaint alleged there were similar generous packages for other specialties, including plastic surgery and acute care surgery.

Whistleblower Said She Was Shut Out of Board Meetings

The physician practices drew the attention of the whistleblower when she was appointed director of internal audit in 2013. Brouse, who reported directly to the board's compliance and internal audit committee, developed a five-year plan that included a review of the practices "because they were consistently showing major losses," according to the complaint. The plan, which was approved by the board of directors, included an analysis of the practices' records. According to the complaint, the financial statements she reviewed "showed they were consistently running at a major loss. The principal factor in these losses was the compensation paid to the physicians."

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Brouse discussed the practice losses at a meeting of the compliance and internal audit committee, and the AGHS CEO responded that she wasn't factoring in the contribution margins. "He explained at that meeting and in other discussions that the physician salaries were an investment in which losses were expected, but would be made up for by hospital revenues other than physician service revenues, generated by the physicians' referrals," the complaint alleged.

Brouse also raised concerns about the alleged above fair market value compensation for plastic surgeons and on-call payments for acute care surgeons. In one conversation, the CEO told her "he will always take the side of the physicians," the complaint alleged. After bringing concerns about alleged FCA violations and physician compensation to the compliance and internal audit committee, Brouse was excluded from its last six meetings in 2015 and fired in December of that year, she alleged in the complaint.

Mendenhall said that Brouse came to him a year before she filed the FCA complaint. She spent a year trying to resolve the problems internally before throwing in the towel. "It's smarter for organizations to take whistleblowers seriously," Mendenhall said. "They are the canaries in the coal mine." Brouse is now a compliance officer at another Akron health care organization, he said.

CCO: 'Losses Can Be Mitigated'

According to the settlement, around March 30, 2016, Cleveland Clinic Foundation, on behalf of AGHS and without knowledge of the FCA complaint, voluntarily disclosed potential violations of the Stark Law and Anti-Kickback Statute to the U.S. Attorney's Office for the Northern District of Ohio "related to AGHS' financial arrangements with certain physician groups."

Sinko said the fact Cleveland Clinic quickly identified the physician compensation problems shows how compliance programs save money. "One of the difficult things compliance departments deal with is showing how their preventive activities, along with auditing and monitoring, provide value. How do you impact the bottom line? How can you document savings? This is an example where if you have an effective compliance program, losses can be mitigated," he said.

Tracking Referrals 'Is the Elephant in the Room'

It's not necessarily a problem for hospitals to lose money on physician practices, said attorney William Maruca, with Fox Rothschild in Pittsburgh, Pennsylvania. "I don't think the lesson from the complaint is you can't pay a doctor more than they generate in professional fees. Health systems often do and intentionally lose money in private practices that support their mission," he said. For example, a rural hospital may employ two neurosurgeons to ensure 24/7 coverage, even though there aren't enough patients to keep their practices busy. But it's risky for hospitals to use contribution margins and other methods to track a physician's referrals, Maruca said. "You're building a case against yourself," he contends. "I think of that as the elephant in the room. It's something the hospital probably shouldn't keep track of." And of course compensation shouldn't be egregious.

Also, the revised Stark regulation,[4] which took effect Jan. 19, clarifies that losing money on a practice is not a deal-breaker under the definition of commercial reasonableness. CMS now states that commercially reasonable means "the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty." Even if nobody profits, or an arrangement results in losses, it may still be commercially reasonable. That seems to strike a blow at the premise of False Claims Act lawsuits that contend hospitals violated the Stark Law when they accepted losses on physician practices in exchange for their referrals.

"Changes in the Stark regulation clarified that the mere fact that a practice doesn't generate enough revenue to break even is not evidence of a lack of commercial reasonableness," Maruca explained. But it's not a license to pay all physicians far more money than they generate from professional services. There has to be a legitimate business purpose for it, he said. For example, if a hospital in Altoona, Pennsylvania, is competing with hospitals in New York City for a specialist, it may have to pay more than the physician generates from fees, as the IRS has recognized for years, he said.

Notwithstanding the Stark revision on commercial reasonableness, "there wasn't any previous rule saying it's not OK" for hospitals to lose money on physician practices, Maruca noted.

The attorney who represented AGHS in the FCA case didn't respond to *RMC*'s request for comment.

Contact Maruca at wmaruca@foxrothschild.com, Sinko at sinkod@ccf.org and Mendenhall at warner@warnermendenhall.com. ✧

Endnotes

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2. Akron General Health System v. Beverly Brouse et al., settlement agreement, June 29, 21, https://bit.ly/2UzOqSl.
3. United States ex rel. Ethical Solutions and Beverly Brouse. v. Akron General Health System, Inc. et al., No. 5:15-cv-2720 (N.D. Ohio).
4. Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 85 Fed. Reg. 77,492 (December 2, 2020), https://bit.ly/3g3eprL.

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Transmittals

Pub. 100-04, Medicare Claims Processing

- July Quarterly Update for 2021 Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule, Trans. 10865 (July 1, 2021)
- July 2021 Update of the Ambulatory Surgical Center [ASC] Payment System, Trans. 10858 (June 25, 2021)

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- October Quarterly Update to 2021 Annual Update of HCPCS Codes Used for Skilled Nursing Facility (SNF) Consolidated Billing (CB) Enforcement, Trans. 10866 (June 29, 2021)

Federal Register

Proposed Rules

- Patient Protection and Affordable Care Act; Updating Payment Parameters, Section 1332 Waiver Implementing Regulations, and Improving Health Insurance Markets for 2022 and Beyond Proposed Rule, 86 Fed. Reg. 35,156 (July 1, 2021)
- Medicare and Medicaid Programs; CY 2022 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model Requirements and Proposed Model Expansion; Home Health Quality Reporting Requirements; Home Infusion Therapy Services Requirements; Survey and Enforcement Requirements for Hospice Programs; Medicare Provider Enrollment Requirements; Inpatient Rehabilitation Facility Quality Reporting Program Requirements; and Long-Term Care Hospital Quality Reporting Program Requirements, 86 Fed. Reg. 35,874 (July 7, 2021)

Final Methodology

- Basic Health Program; Federal Funding Methodology for Program Year 2022, 86 Fed. Reg. 35,615 (July 7, 2021)

Correction

- Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; Physician-Owned Hospitals; Notice of Closure of Two Teaching Hospitals and Opportunity To Apply for Available Slots, Radiation Oncology Model; and Reporting Requirements for Hospitals and Critical Access Hospitals (CAHs) To Report COVID-19 Therapeutic Inventory and Usage and To Report Acute Respiratory Illness During the Public Health Emergency (PHE) for Coronavirus Disease 2019 (COVID-19), 86 Fed. Reg. 33,902 (June 28, 2021)

OIG: Focus Is On COVID-19 Response, Plans to 'Re-imagine' Guidance

There are parallels in the way that messenger ribonucleic acid (mRNA) vaccines help the body defend against COVID-19 infection and the way compliance professionals, health care attorneys, executives and inspectors general carry out their roles. They provide a road map to organizations to protect themselves like the vaccines do, HHS Principal Deputy Inspector General Christi Grimm said June 29 at the American Health Law Association (AHLA) annual meeting.

"We serve to protect an organization and the people that organization serves—by showing them how to protect themselves. And, like the new Messenger RNA vaccines, our work typically involves providing a blueprint and some level of instructions, that, if followed, protect now and provide lasting immunity well into the future," she said.[1] "I suspect you play a similar role, giving instructions on how to guard against any number of legal, operational, and compliance issues. You might be thinking this metaphor is a bit of a stretch, but the comparison is both instructive and encouraging… The messenger RNA vaccines are just one part of this potential change. The question—and challenge for us now—is whether this inflection point is the spot on the timeline where we also collectively address consequential problems that have continued, resulting in significant effects on patients, providers, and health care programs."

She addressed four issues in this context:

1. **Ensuring the integrity and effectiveness of response and recovery from the pandemic**. Congress has invested more than $5 trillion in COVID-19-related relief since 2020, which Grimm said exceeds all federal spending in 2019. "Unfortunately, but not unexpectedly—we have seen bad actors exploiting the pandemic to cause harm and line their pockets," she said. The HHS Office of Inspector General's hotline has received 2,400 complaints of purported COVID-19 fraud since the pandemic began. "Law enforcement and oversight agencies across Federal, State, and local governments are working together in unprecedented ways to share data and trends, provide transparency around where the money is going, and to respond quickly and aggressively to mitigate schemes that jeopardize public health efforts and the health and safety of people," she said. For example, the attorney general in May announced the creation of the COVID-19 Fraud Enforcement Task Force. OIG also has 60 reviews underway of HHS programs, funding and response, including audits of the Provider Relief Fund and the Health Resources and Services Administration's COVID-19 Uninsured Program.
2. **Ensuring quality of care and patient safety in nursing homes**. In June, OIG released a report that found overall mortality in nursing homes rose by almost a third in 2020 compared to 2019.[2] The pandemic didn't affect residents equally, according to the report. "About half of Black, Hispanic, and Asian beneficiaries in nursing homes had or likely had COVID-19, compared to 41 percent of white beneficiaries," Grimm said. "We cannot wait for another pandemic to address long-standing

issues like the need for improved infection control, reporting of incidents of harm, staffing, and effective Federal and State oversight."

3. **Advancing health equities**. COVID-19 also demonstrated "how stark racial and socioeconomic disparities in our country have significant negative effects for health outcomes," Grimm said. OIG has plans to address disparities "by considering how our work can incorporate objectives related to equity, social determinants of health, and their effects on health experiences and outcomes," she said. "And like many of you, we are also turning an inward lens to ensure that our own organizational culture fully embraces diversity, equity, and inclusion in action as well as word."
4. **Realizing the potential of telehealth**. Policy discussions are underway about the future of telehealth "and we want to ensure program integrity is appropriately considered," Grimm said. "Effectively expanding telehealth and ensuring program integrity will take effort on a number of fronts that may not be considered traditional compliance issues: cybersecurity, interoperability, and patient access to technology."

OIG Has Initiative to Rethink Guidance

Grimm said OIG also has an initiative underway to "re-imagine" the kinds of guidance and other resources it provides, including advisory opinions, special advisory bulletins, special fraud alerts, toolkits, compliance program guidance and the COVID-19 answers to frequently asked questions. "Additionally, we're exploring a number of ways to improve how OIG data are provided to the health care industry and others. We want to provide things like self-service tools," she said.

For example, in May, OIG published data on its website about substance use disorder through a new, interactive web-mapping application. "This tool can be used to drill down into data about how the substance use disorder epidemic is affecting your city, county, or state, available treatment options, and other information with just a few clicks on a map," she said. OIG also has plans to use application programming interfaces to improve exclusion screening with the List of Excluded Individuals/Entities. "Your input and insights will also help us find preferred approaches for deploying other APIs, self-service tools, and additional modern data sharing practices to make it easier to access and use program integrity data," she said.

Fauci: Equity in Health Care 'Is What We Need'

Anthony Fauci, M.D., chief medical adviser to President Joe Biden, also spoke at the AHLA annual meeting about COVID-19, health disparities and other issues. On people with vaccine hesitancy, Fauci said "you have to treat them with respect" and "try to get them to discuss with you the reasons." Sometimes the reasons people won't get vaccinated are "based on misinformation," he said. "Make sure people have the correct information to make a decision." The best way is by using "trusted messengers," including religious leaders and family members.

The health disparities exposed by COVID-19 are "quite disturbing." Not only were many people of color more susceptible to infection because of their jobs, which often put them in contact with infected people, but they have a greater incidence of underlying conditions (e.g., diabetes, hypertension, chronic renal disease) that make them more vulnerable to the severe consequences of COVID-19, Fauci said. "Those are not racially determined. Those are the results of the social determinants of health," he explained. "Equity and accessibility is absolutely critical. We can't have systems that propagate disparities." ✧

Endnotes

1. Christi A. Grimm, "PDIG Keynote Address," American Health Law Association Annual Meeting, June 29, 2021, https://bit.ly/3yEbm1y.
2. HHS, "COVID-19 Had a Devastating Impact on Medicare Beneficiaries in Nursing Homes During 2020," OEI-02-20-00490, June 2021, https://bit.ly/3x2zpqA.

Rulings May Affect Overpayment Findings

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Truitt said when auditors start out, they "always maintain the single, unique and complete dollar value of the claim. If I have a claim with three line-items on it, one of which is an unpaid zero dollar value item, one of which is a negative dollar adjustment and the other is a positive dollar amount, leaving out the negative dollar adjustment will affect the total dollar value of the claim. And, if I sample at the line-item level, leaving out the zero dollar unpaid item will affect the total size of the sampling frame from which I pull the sample."

'Sampling Size Must Include All Underpayments'

The June ALJ decision, which the attorney shared with *RMC*, focused on claims submitted by a DME supplier mostly for knee orthoses and spinal orthoses that were denied by a zone program integrity contractor (ZPIC) after a postpayment review. The ZPIC used stratified random sampling, with paid amounts serving as a proxy for stratifying by overpayment amounts, which are unknown before sampling.

After making some headway in its appeal to the qualified independent contractor, the DME supplier took its challenge of the sampling method and extrapolation to the ALJ. Although Dr. Cox, the statistician for the DME supplier, argued there were five reasons why the

ZPIC's sampling methodology was flawed, Bittinger said the unpaid claims argument is the game changer.

According to the ALJ opinion, Cox argued that "regarding the composition of the universe of claims," Chapter 8 of the *Medicare Program Integrity Manual* "cannot be interpreted to allow the removal of the unpaid or zero-paid service lines from the universe. As a result, the net overpayment was not considered, only the gross overpayment. Sampling size must include all underpayments and zero paid claims and all must be extrapolated to determine the net overpayment. AdvanceMed [the ZPIC] included claim numbers that had multiple individual codes and dates of service, then they removed the individual codes and dates that were not paid. When they remove zero paid line items, the claims are never audited and there is never the opportunity to review for mistakes and potential payment. By removing the zero paid claims they remove the possibility of finding an underpayment. Medicare requires that these zero paid items must be included and reviewed. Not a valid sample due to the lack of the zero paid claims. Sample not properly designed."

The ALJ agreed with the statistician on this point and four others. The five reasons "for invalidating the statistical sample are accurate," ALJ Marc Lambert wrote. As a result, "the statistical sample for the claims at issue is considered invalid."

MAC Chief Statistician Saw Things the Same Way

The ALJ decision comes on the heels of a similar opinion from the chief statistician at CGS Administrators, a MAC for durable medical equipment, prosthetics/orthotics supplies (DMEPOS). "The reason it was so significant is it was the first time any statistician at any level has agreed with the position that the exclusion of zero or underpaid claims is important," Bittinger said. The chief statistician's opinion came down in connection with Bittinger's appeal on behalf of another DME supplier audited by the HHS Office of Inspector General (OIG). After auditing a single universe of claims submitted by the DME supplier to four MACs that process claims in different jurisdictions, OIG identified overpayments.

In its appeal, the DME supplier's statistical expert objected to OIG's audit methodology and the MAC chief statistician agreed with some of the arguments, although possibly for different reasons. "I found the information provided by the OIG to be insufficient to replicate the sample pull," she wrote. "This issue alone invalidates the sampling and overpayment estimate of $1,858,630." As a result, recovery must be based on the actual overpayment amount, according to the *Medicare Program Integrity Manual*. That figure was less than $8,000 for her MAC's two jurisdictions.

The chief statistician explained that when "a beneficiary is the sampling unit," which was the case in the OIG audit, "all lines for all claims for each beneficiary containing any of the codes of interest should be in the universe, including whole claims paid $0. These $0 paid claims, if they exist, are in the cluster of claims that make up a beneficiary sampling unit and cannot be omitted. The $0 paid claim would be reviewed for potential underpayment just as $0 paid lines must be reviewed when the sampling unit is a claim. Claims paid $0 dollar may not exist in this case, but I cannot determine that because the OIG filtered out claims paid $0 when creating the universe," the chief statistician wrote.

She backed up her position by noting that Chapter 8 of the *Medicare Program Integrity Manual* (Sec. 8.4.3.2) states that "the sampling frame includes all sampling units which were paid" and "when sample units are clusters, there may be lines or claims included which did not individually generate payment."

OIG could correct the sampling problem and generate an accurate extrapolated amount by taking a few steps, the chief statistician said. One of them: "They would need to locate within their data repository any existing $0 paid claims with a HCPCS of interest for the beneficiaries in the sample and review to determine if any underpaid amounts should be netted from the individual beneficiary overpayments and a re-extrapolation performed," she explained.

The message of the ALJ decisions and the MAC chief statistician's opinion is that providers should challenge the validity of the sampling and extrapolation methodology earlier, especially with big dollars at stake, Bittinger said.

OIG: Including Zero-Paid Claims May Cost Providers More

But Stephen Conway, a director in OIG's Office of Audit Services (OAS), told *RMC* that the *Medicare Program Integrity Manual* (MPIM) chapter on Administrative Actions and Sanctions and Statistical Sampling for Overpayment Estimation doesn't apply to OIG. "For additional context, even if it did apply to OIG, the MPIM expressly allows for the removal of 'claims/claim lines [that] are attributable to sample units for which there was no payment,'" he said. "More generally, OIG may perform a statistical or nonstatistical review of a provider without covering all claims from that provider. Furthermore, OIG's statistical estimates are applied to only the frame from which the sample was drawn. If the Office of Audit Services (OAS) included zero-paid claims in its sampling frame, it is likely the estimated amount owed by the provider would be more."

Conway added that federal courts have repeatedly upheld the use of statistical sampling and extrapolation to determine Medicare and Medicaid overpayment amounts. "The legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology," he said. "On all audits which use statistical sampling, OAS properly executes its statistical sampling

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Q&A: Clearing the Air on Some Aspects of Sampling and Extrapolation

Here are answers to some fundamental questions about sampling and extrapolation, which are key to auditing and overpayment findings (see story, p. 1).[1] They were provided by auditor/statistician Bruce Truitt, a former faculty member of the Medicaid Integrity Institute in Columbia, South Carolina, who said these concepts are often misunderstood. Contact him at brucetruitt@gmail.com.

PROGRAM INTEGRITY SAMPLING AND EXTRAPOLATION CONVENTIONAL WISDOM IS AT TIMES NOT SO WISE

Here we explore some "conventional wisdom" and indicate areas that have been addressed in specific cited cases.

Can Statistical Sampling Be Used?

The seminal case is *Chaves County Home Health Servs. v. Sullivan,* in which the court judicially approved sample adjudication despite the lack of specific reference to it in the Medicare Act. See also *Michigan Dept. of Educ. v. United States*, *Mile High Therapy Centers, Inc. v. Bowen, United States v. Smushkevich*, *Illinois Physicians Union v. Miller*.

In *Ratanasen v. Cal. Dept. of Health Servs.*, the court rejected the objection that reaching a true overpayment required examining each file on its own and found that a simple random sampling approach to calculating liability was valid.

In *Georgia v. Califano*, the court found that "Projections of the nature of a large population through review of a small number of its components has been recognized as a valid audit technique and approved by federal courts," citing *New Jersey Welfare Rights Organization v. Cahill* and *Rosado v. Wyman*. Similar ruling arose in *United States v. DeCosmo*.

The *Georgia* case also concluded that "Audit on an individual claim-by-claim basis of the many thousands of claims submitted each month by each state would be a practical impossibility as well as unnecessary."

Is the *Medicare Program Integrity Manual* Binding?

Guidance and Memoranda apply but are not binding. "ALJs [administrative law judges] and the MAC [Medicare administrative contractor] are not bound by Local Coverage Determinations, Local Medical Review Policies, or CMS program guidance, such as program memoranda, and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case" (42 C.F.R. § 405.1062-1063).

Does the Administrative Law Judge Have to Consider the Entire Sample?

Yes, the Administrative Law Judge must consider the entire example. "When an appeal from the QIC involves an overpayment issue and the QIC used a statistical sample in reaching its reconsideration, the ALJ must base his or her decision on a review of the entire statistical sample used" (42 C.F.R. § 405.1064).

Do 'Generally Accepted Statistical Principles and Procedures' Exist?

The courts have not adopted specific methodological guidelines. The Medicare Appeals Council and Federal Courts have held that there is no formal recognition of "generally accepted statistical principles and procedures" (*Michael King, M.D. and Kinston Medical Specialists, P.A. Cigna Government Services Claim for Part B Benefits*, *Alpine Home Care, Cahaba Government Benefit Administrators Claim for Part A Benefits*, and *Pruchniewski v. Leavitt*).

How Important Is Sample Size or a Sample's Percentage of the Population?

The courts have held that no statistical floor for sample size exists (*Webb v. Shalala*) and that sampling a percentage of the population is irrelevant, noting use of a .4% sample in (*Michigan Dept. of Education*). Moreover, in *Pruchniewski v. Leavitt*, the judge rejected plaintiff arguments that a sample size of 30 was too small to be reliable, that a sample size of 320 was necessary, and that a sample of 320 would have produced an estimated overpayment that was below the lower limit of the 90% confidence level calculated by the carrier.

Courts have further noted that confidence intervals account for imprecision from a smaller sample size (*Border Ambulance Service, LLC TrailBlazer Health Enterprises Claim for Part B Benefits* and *Transyd Enterprises LLC Trailblazer Health Enterprises LLC Claim for Part B Benefits*). American Institute of Certified Public Accountants (AICPA) adds that all random samples are "representative" and that representativeness relates to selection method and has nothing to do with sample size.

How Important Is Precision?

The MAC and Federal courts have hesitated to set aside statistical sampling and extrapolation in response to claims that the overpayment was imprecise without also showing that it was arbitrary and capricious, especially demand amounts are at the lower confidence limit (*Foot and Ankle Associations of NC, PLLC, AdvanceMed Claim for Part B Benefits*, *John Sanders, M.D. CIGNA Government Services Claim for Part B Benefits*, *John v. Sebelius*, and *Pruchniewski v. Leavitt)*.

Must Population and Sample Means or Proportions Be Statistically the Same?

State of New York v. Rite Aid of New York, Inc. found that failure to match the population dollar mean and sample dollar mean is neither necessary nor likely in a valid estimate. Also rejected was comparing the proportion of patients-to-claims in the sample to the proportion of patients-to-claims in the universe.

Is Stratification Required?

While CMS (and AICPA) recognize that stratification may afford greater precision, the MAC and courts have held that failure to stratify does not disqualify the results, especially absent demonstration that a different stratification would have made a significant difference in the overpayment estimation (*Diana Carneal, OTR, D/B/A The Muscle Manager Western Integrity Center (PSC) Claim for Part B Benefits*, *Pruchniewski v. Leavitt*, and *Ratanasen v. State of California*). In HCA v. Kansas, failure to stratify was ruled not to affect the reliability of the sample. *State of New York v. Rite Aid of New York, Inc.* noted that, while stratification might give a more *precise* estimate, it is not required for a *valid* estimate.

Endnotes

1. Nina Youngstrom, "Rulings: Sampling, Extrapolations Should Include Underpayments, Unpaid Claims," *Report on Medicare Compliance* 30, no. 25 (July 12, 2021).

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methodology in that it defines the sampling frame and sampling unit, randomly selects the sample, applies relevant criteria in evaluating the sample, and uses statistical sampling software (i.e., the OIG, OAS, statistical software RAT-STATS) to apply the correct formulas for the extrapolation."

CIA Claims Review Approach Has Changed

Depending on the circumstances, government audits may include underpayments. Audits conducted under the Improper Payments Elimination and Recovery Improvement Act (IPERIA) include underpayments, Truitt said. "If I do an IPERIA audit, and I come across a claim that is underpaid by $10, I count that as a $10 improper payment, and it goes in with all the overpayments because the thing I am interested in is how many (the gross number of) dollars should not have been paid at all in either direction," Truitt explained.

In recent years, however, some CMS and OIG auditors have moved away from including underpayments in random samples, Truitt said. For example, audits conducted in connection with OIG corporate integrity agreements (CIAs) no longer take underpayments into account, he said. "What they're interested in now is only an overpayment error rate. They changed the way they do the analysis. The new CIAs say if you come across an underpayment, you enter it as zero when extrapolating."

Susan Gillin, chief of OIG's Administrative and Civil Remedies Branch, explained that OIG changed its CIA "claims review approach from one that required a Discovery Sample and, if the error rate from that Discovery Sample was 5% or greater, a Full Sample, and that approach allowed for 'netting' of underpayments. In the current claims review approach, there is just a single sample of paid claims (usually 100) and the error rate is calculated based only on the overpayments as a percentage of the total amount paid. "

OIG's Office of Audit Services, which conducts Medicare compliance reviews/provider compliance audits, often reports findings as "net overpayments." That's a reference to overpayments minus underpayments. "For those audits that involve situations where, through medical review, it is determined that a provider could have been reimbursed more than it was for a particular service, OAS does take into consideration underpayments and nets those against any overpayments. OAS uses the term 'net overpayments' as appropriate when reporting sample results and estimates," Conway explained.

Truitt thinks the bottom line is that sometimes Medicare auditors "don't give the provider credit" for underpayments or claims that Medicare never resolved. "They are biasing the game in their favor."

He understands the reason. The government's goal is to protect the Medicare Trust Fund, not a health care organization's bottom line. "It's not necessarily that anyone is doing anything wrong here," Truitt said. "But the provider has not been given an equal seat at the table. It's a classic case of competing objectives for pulling a sample."

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Endnotes

1. CMS, "Chapter 8 – Administrative Actions and Sanctions and Statistical Sampling for Overpayment Estimation," *Medicare Program Integrity Manual*, Pub. 100-08, October 9, 2020, https://go.cms.gov/32woneV.

NEWS BRIEFS

◆ **CMS's supplemental medical review contractor added a new audit July 7**. It will conduct a post-payment review of a sample of Part B claims for Medicare Vitamin D laboratory test services billed in 2019.[1]

◆ **St. Jude Medical Inc. has agreed to pay $27 million to settle false claims allegations that between November 2014 and October 2016** it "sold defective heart devices to health care facilities that, in turn, implanted the devices into patients," the Department of Justice said July 8.[2] Abbott Laboratories acquired St. Jude in January 2017.

◆ **The U.S. Supreme Court has agreed to hear the American Hospital Association's (AHA) appeal of CMS's nearly 30% reimbursement cut to 340B drugs**. The petition for certiorari was accepted by the high court July 2. CMS decreased reimbursement for 340B drugs and biologicals from average sales price (ASP) plus 6% to ASP minus 22.5% in the 2018 Outpatient Prospective Payment System regulation. AHA sued and won in federal district court, but that decision was reversed at the U.S. Court of Appeals for the D.C. Circuit. AHA and other hospital associations then asked the Supreme Court for relief.

◆ **CMS has updated its answers to frequently asked questions on COVID-19 Accelerated and Advanced Payments.**[3]

Endnotes

1. "01-049 Vitamin D Testing Notification of Medical Review," Noridian, updated July 7, 2021, https://bit.ly/3yzuOfO.
2. Department of Justice, "St. Jude Medical Agrees to Pay $27 Million for Allegedly Selling Defective Heart Devices," news release, July 8, 2021, https://bit.ly/36mlD66.
3. CMS, "COVID-19 Accelerated and Advance Payment (CAAP) Repayment & Recovery Frequently Asked Questions," updated June 24, 2021, https://go.cms.gov/3dXNdeg.