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QUI TAM QUARTERLY

COVID-19 AND THE BIG-DATA REVOLUTION OF HEALTH CARE FALSE CLAIMS ACT LITIGATION

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The regulatory scheme governing the submission and payment of claims for health care services to government payers is complex and convoluted. It is a slippery slope for the unaware or ill informed. The health care claims system is predicated on the concept that the government pays submitted claims without review or comment and thereafter seeks to recover improper payments—including through the potential application of penalties and damages—if providers do not adhere to the relevant regulations. That system became exponentially more complex as a result of COVID-19, which created a staggering number of regulatory changes to the system since March 2020.

In 2019, even without these dramatic changes, Medicare and Medicaid accounted for US$103.6 billion of improper payments, and the Department of Justice (DOJ) recovered US$2.6 billion of improper health care payments on the basis of asserted False Claims Act (FCA) liability. As a result, the government and relators have turned to a new and growing tool to investigate and pursue health care FCA actions: statistical sampling and extrapolation of mass claims data. The industry has recently seen the results of the government's use of this tool in Operation Brace Yourself, Operation Double Helix, and the massive US$6 billion Health Care Fraud Takedown announced in September 2020.

The tidal wave of reimbursement-related regulatory change brought on by COVID-19 will force relators and the DOJ to rely on big-data analysis in FCA litigation in an unprecedented manner. The Office of Inspector General (OIG) for the U.S. Department of Health and Human Services (HHS) has already reported to Congress an anticipated US$4 billion in expected recoveries for FY2020 with US$942 million based on audit findings and more than US$3.14 billion based on investigation recoveries, which includes 791 civil actions for false claims and unjust-enrichment.[1] In addition, the Office of the General Counsel for HHS just announced the formation of a FCA Working Group comprised of former FCA and health care fraud prosecutors, former private counsel for health care and life science companies, and HHS attorneys to investigate the more than US$1.5 trillion in grants and payments disbursed in 2020.[2]

This edition of *Qui Tam Quarterly* focuses on:

- the history of big data in health care FCA investigations and litigation;

- how the government has increased its ability to gather health care claims data and use it to support FCA allegations;

- how big data will most likely be used as a primary tool for investigations to evaluate potential fraud due to regulatory changes brought on by COVID-19; and

- how providers can use big claims data to control discovery costs in investigations and to better understand the operations of their compliance programs to prevent improper claims from being filed.

This edition concludes with key strategies for defending allegations supported by extrapolated overpayments and some best practices for using claims data to proactively defend against scrutiny. Specifically, information and recommendations are provided on how to undermine the validity of findings on a sample set of claims that can be used to invalidate the extrapolated assumptions, how to effectively challenge an extrapolation based on improper sampling and auditing processes, and how to dispute

the statistical extrapolation process after an extrapolated overpayment has been asserted against a provider. Finally, resources and suggestions are provided on how providers can take advantage of currently available claims data to reduce the risk of scrutiny.

The Scope of Improper Health Care Payments and Origins of Proving They Were Fraudulent

To evaluate the potential improper payment of health care claims by government payers due to the regulatory changes brought on by the pandemic and the scope of FCA liability that may be asserted, it is appropriate to consider the results from the most current pre-pandemic year and how big data came to be used to support FCA liability during that period. In fiscal year 2019 alone, Medicare and Medicaid accounted for US$103.6 billion of improper payments made by the government, which was 59 percent of all government-wide estimated improper payments during this year.[3] Within that figure, Medicare fee-for-service accounted for US$28.9 billion with an error rate of 7.3 percent, Medicare Advantage plans attributed for US$16.7 billion with an error rate of 7.9 percent, and Medicaid was US$57.4 billion with an error rate of 14.9 percent.[4] While these figures include all error-based payments and potentially fraudulent claims paid, a comparison to the DOJ's results from last year is useful to consider how the rate of both may increase due to regulatory changes brought on by the pandemic. In 2019, the DOJ reported recovery of over US$3 billion from 782 FCA cases, US$2.6 billion (87 percent) of which was health care related.[5] As the vast majority of FCA health care cases rest on providers' submission of improper claims data, an understanding of how the government and relators use such vast amounts of information is warranted.

Statistical extrapolation, where findings on a sample set are presumed to accurately reflect the same result across a universe of claims, is one of the most powerful weapons of relators and the government in prosecuting health care FCA cases. Although extrapolation may seem commonplace today, understanding the origin of its use and its limitations can make all the difference in defending the presumptions this weapon can raise. The solidification of statistical extrapolation as a credible means of proving a mass amount of health care claims were invalid or false without a claim-by-claim review gave birth to the use of big data to prove fraud in health care false claims litigation. In 1986, the Health Care Financing Administration (HCFA), the predecessor to the Centers for Medicare and Medicaid Services (CMS), ruled that a contract auditor was

permitted to use sampling and extrapolation as opposed to a claim-by-claim review because: (a) the government has a significant interest in cost-effective recovery of improper payments; (b) even though there was no express authorization, there was also no express prohibition; and (c) providers were not denied due process because of their ability to appeal extrapolated findings through the administrative appeals process.[6] Before unpacking how extrapolation has evolved in FCA litigation, it is important to understand the government players and programs involved in gathering and producing the data that underlies the presumptions made by extrapolation.

Perhaps the most central in all health care fraud analysis throughout the U.S. health care system is the CMS Center for Program Integrity (CMS-CPI), a specific division of CMS that is the focal point of all national and statewide Medicare, Medicaid, and Children's Health Insurance Program integrity fraud and abuse issues.[7] CMS-CPI oversees all CMS interactions and collaborations with stakeholders relating to program integrity, including the DOJ, HHS-OIG, state law-enforcement agencies, and other federal entities for the purpose of detecting, deterring, monitoring, and combating fraud and abuse, as well as taking action against those that commit or participate in fraud.[8] CMS-CPI is the heart of health care fraud investigation, and the claims data is the blood that it pumps through the Fraud Prevention System (FPS)—a complex software system the reads and analyzes the more than 1 billion claims processed per year.[9] However, access to CMS-CPI's data warehouse in the FPS is not limited to just federal payers.

In 2012, CMS-CPI began the Health Care Fraud Prevention Partnership with 20 public and private partners focused on data and information sharing, which has now grown to include 181 partners.[10] More recently, CMS-CPI began the Major Case Coordination program, which is a collaboration between CMS-CPI, HHS-OIG, and DOJ that led to large-scale takedowns like Operation Brace Yourself[11] and Operation Double Helix.[12] The collection, analysis, and dissemination of claims data was at the heart of these operations.[13] 2020 has proved to set new records in this arena, with the National Health Care Fraud Takedown in September[14] resulting in 345 defendants charged, including more than 100 medical professionals and an alleged fraud loss of more than US$6 billion, with the largest amount of the alleged loss—US$4.5 billion—involving telemedicine, the most changed method of delivery of services during the pandemic. Understanding how these multidistrict and national cases originate and evolve with the assistance of data analysis requires a look at how the law has changed in regard to the application of data in the FCA legal framework.

Relators' Use of Big Data in Health Care FCA Cases

Government enforcement agencies have become increasingly well equipped to analyze and use big data to detect and prosecute fraud. In 2017, the DOJ Criminal Division's Health Care Fraud Unit announced the launch of a "data analytics team" aimed at both identifying fraud and assisting with current prosecutions.[15] HHS-OIG also has encouraged state governments to use data mining to identify potential Medicaid fraud. CMS's Head Administrator Seema Verma stated that the organization was "moving to a system where we're able to take quality data from the EHR [electronic health record], we can combine it with claims data, we can see what's going on in program integrity . . . in a way, that's been fairly unprecedented."[16] The increased use of data analytics in fraud detection and prosecution is on the rise following the government's COVID-19 response, but it is not limited to government enforcement agencies alone.[17] Private relators have become key players in the FCA litigation landscape.[18] The COVID-19 crisis has set up a backdrop ripe with opportunity for private parties to recoup substantial monetary compensation by bringing FCA claims on the basis of data mining. According to the DOJ, of the approximately US$3 billion in FCA settlements filed in 2019, over US$2.1 billion arose from qui tam litigation, resulting in over US$265 million in payouts to individual relators.[19] Through tracking publicly available information, these private relators can detect abnormalities in claims data and pinpoint trends that fall outside of the normal deviations from the mean, thus equipping them with the building blocks of an FCA lawsuit. Moreover, the relaxation of many regulatory requirements, such as those in telemedicine, will likely lead providers to engage in more high-risk behavior and, in turn, cause good-faith billing/coding errors, inaccurate certifications and documentation, and other anomalous data to instead serve as indicators of FCA violations.

Sampling and Presumptions

The mechanics of data analytics within the FCA context can be broken down into two generalized processes: statistical sampling and extrapolation. Statistical sampling is when random number generation is used to select a subset of a discrete population. Extrapolation is the second step of the process, where values are extended by inferring unknown values from trends in the known data in order to make determinations about the population as a whole. If done correctly, this is a highly effective way to predict patterns in data. If done incorrectly, it can manifest a warped representation of reality.

The technique of statistical sampling has been used to varying degrees of success by many relators. For example, in *United States v. Cabrera-Diaz*,[20] statistical sampling was used to establish FCA liability for claims submitted under Medicare. The issue of whether statistical extrapolation was appropriate came before the court when the defendant failed to appear and the government moved for a default judgment. While the court held that it was appropriate, the holding has been limited by the procedural posture of the case. For example, in *United States ex rel. Martin v. Life Care Centers of America, Inc.*,[21] the court noted that Cabrera-Diaz was limited in significance given that "[w]ithout evidence and argument opposing the government's position, the Court cannot view the result in *Cabrera-Diaz* as anything other than an unopposed remedy suggested by the government, which was granted through a procedural mechanism to obtain judgment from unresponsive parties."

In *United States ex rel. Loughren v. UnumProvident Corp.*,[22] statistical sampling was used to extrapolate the total number of false claims for the purpose of determining damages. However, this was allowed only after the court held a bellwether jury trial to determine whether sufficient evidence existed regarding defendant's pattern and practice of submitting false claims. Accordingly, despite supporting the use of extrapolation, *Loughren* can be limited to the robust mechanisms put into place by the court to evaluate intent. Other courts have allowed extrapolation only when claim-by-claim review is impracticable.[23] However, in U*nited States ex rel. Michaels v. Agape Senior Community, Inc.*,[24] the court reached the opposite conclusion.

In *Agape*, relators filed an FCA lawsuit against a network of nursing homes, alleging the nursing homes fraudulently submitted claims for services that were not medically necessary to Medicare, Medicaid, and TRICARE. The court described the case as involving a "staggering" number of claims. Relators retained two experts, and estimated that individualized review of all the claims at issue would cost between US$16 million and US$36.5 million. The court initially declined the use of statistical extrapolation at the discovery stage but later encouraged the parties to hold a bellwether trial involving a small sample of the allegedly false claims as a test to the veracity of the larger set of alleged false claims. Although the parties agreed to undergo the bellwether trial, they settled prior to its occurrence, to which the government objected and filed an interlocutory appeal. Following the appeal, the Fourth Circuit heard argument on (1) whether statistical sampling could be used to establish liability in a FCA case, and (2) whether the government could veto a FCA settlement in a case in which it had declined to intervene. The Fourth

Circuit ruled that the government did possess the authority to veto a settlement in a nonintervened case, and refused to address whether sampling could be used to establish liability. This, once again, left an open question as to the viability of extrapolation as the basis for support in FCA cases.

Moreover, another point of contention across circuits is the application of the FCA's public disclosure bar, which prohibits relators from filing qui tam suits based on "substantially the same allegations or transactions" that were publicly disclosed in a government "report."[25] The Supreme Court has construed "report" broadly to include "something that gives information or a notification."[26] Accordingly, some lower courts have concluded that information published online by the government, including CMS claims data, can trigger the public disclosure bar. Before litigating the standards to be applied to sampling and extrapolation, a careful analysis should be performed of the process used by the auditor to support health care FCA claims.

1. Auditors' Role in Government-Initiated Health Care FCA Litigation

Although many litigators are aware that government audits are often involved in the origins of a FCA case, many may not be aware that the DOJ is directly collaborating with CMS contract auditors and that government-initiated FCA cases may originate from the referral of auditors. Unified Program Integrity Contractors (UPICs) have become the primary vehicle for CMS to investigate and data-mine for fraud in Medicare and Medicaid claims processing.[27] UPICs perform integrity work with Medicare Parts A and B, durable medical equipment, Home Health and Hospice, Medicaid, and the Medicare-Medicaid data match program.[28] The UPIC program was specifically created with the intent to consolidate all CMS integrity work to facilitate better coordination with the CMS-CPI, the Federal Bureau of Investigation (FBI), HHS-OIG, DOJ, and local law enforcement.[29]

UPIC regulations and guidance create an avenue to report suspected fraud to CMS-CPI, HHS-OIG, FBI, and DOJ.[30] UPICs gather data analysis leads that uncover inexplicable aberrancies that indicate potentially fraudulent, wasteful, or abusive billing for specific providers/suppliers.[31] UPICs also assist in ongoing investigations at the request of HHS or DOJ that involve national interagency initiatives or projects, cases with a likelihood of an increase in the amount of fraud or enlargement of a pattern, multi-state fraud, and high-dollar amounts of potential overpayments or other administrative actions (e.g., payment suspensions and revocations).[32] UPICs and their employees and professional consultants are protected from criminal and civil liability as long as their duties were performed with due

care in the course of their contract.[33] UPICs are required to maintain all their work in the Unified Case Management (UCM) system.[34]

The UCM is a national database that UPICs use to enter Medicare and Medicaid fraud, waste, and abuse data analysis projects, leads, and investigations initiated by UPICs.[35] UPICs use the UCM to track administrative actions, requests for assistance, and requests for information from law enforcement. The UCM is currently accessible by UPICs, the National Benefit Integrity Medicare Drug Integrity Contractor, the Railroad Retirement Board, CMS contractors (FPS, PIMAS, Acumen, IBM), Medicare Administrative Contractors (MAC), Medical Review Units associated with MPIP, CMS, FBI, DOJ, HHS-OIG, and other federal and state partners seeking to address program integrity concerns in judicial or state health care programs.[36] The UCM is a live-feed from UPIC auditors to the DOJ, and the DOJ has become increasingly effective in using this big-data tool to investigate and prosecute civil and criminal FCA cases on national cases.

In a 20 November 2020 press release by the DOJ, the U.S. Attorney's Office for the District of Minnesota highlighted a FCA case initiated by the government against two medical laboratories, their owner, and an employee.[37] Although the settlement amount of US$500,000 based on ability to pay and exclusions are not of significant note, it is of interest that this settlement was based on the government's own case against the defendants for their role in "knowingly causing" other providers to submit false claims for medically unnecessary services. The release goes on to highlight that this upstream liability asserted against the defendants was based on "a proactive government investigation based on a critical analysis of Medicare claims data." Lamont Pugh, III, Special Agent in Charge for HHS-OIG, Chicago Region, was quoted as stating, "The OIG routinely conducts data analysis in an effort to identify aberrant and potentially fraudulent billing trends and will take action to hold accountable those who seek to defraud federally funded health care programs."

With HHS-OIG's 2 December 2020 release of their Semiannual Report to Congress highlighting an expected recovery in excess of US$4 billion for claims paid during FY2020, the spotlight turns to services that saw the most dramatic regulatory changes.[38]

2. How Big Data May Be Used to Support Health Care FCA Cases Based on COVID-19 Changes

HHS-OIG has indicated that it intends to strengthen enforcement efforts by coordinating with other HHS officials and oversight partners to identify vulnerabilities, patterns, and trends of suspicious activity.[39] In addition to widespread coordination, it is clear from recent takedowns

and FCA actions that the tools and methodologies used to analyze big data are becoming more sophisticated. Today, data analytics are regularly employed to proactively identify potential instances of fraud.

According to the HHS-OIG Strategic Plan (2020–2025), the OIG will utilize advanced data analytics, artificial intelligence, and machine learning to more effectively perform risk assessments across HHS programs, provider types, and geographic locations to predict vulnerable services that may be susceptible to fraud, waste, and abuse.[40] The DOJ has indicated that the FCA will be among the primary means of combatting fraud relating to the COVID-19 relief package. On 26 June 2020, the DOJ published remarks from the Principal Deputy Assistant Attorney General of the DOJ's Civil Division, Ethan P. Davis, which highlighted the Civil Division's approach to combating fraud related to the various COVID-19 stimulus programs.[41] Davis emphasized that the DOJ's Civil Division will "energetically use every enforcement tool available to prevent wrongdoers from exploiting the COVID-19 crisis," noting that the FCA is one of the "most effective weapons in [the Civil Division's] arsenal."

Utilizing data analytics in 2020 will likely present challenges unique to the context of the public health emergency (PHE). While modern data analytics will continue to support enforcement actions, relying on patterns and trends identified in an ever-changing web of enforcement discretion and regulatory flexibility will not always yield consistent, reliable results. While the DOJ, HHS-OIG, CMS, and other agencies central to enforcement measures express a strong commitment to identifying and combating fraud related to the COVID-19 stimulus programs, it will be essential to distinguish good-faith actors attempting to comply with regulatory changes from individuals who intend to take advantage of relaxed requirements to commit fraud. Overly aggressive enforcement efforts could stifle expedited production of vital resources that are needed to effectively respond to the PHE.

While there is a general concern that suppliers and providers working to respond to the needs of the pandemic will be overburdened by the daunting task of keeping pace with regulatory flexibilities and policy changes, the DOJ is committed to striking a balance between combatting fraud and enabling and efficient and innovative response to the PHE. In the DOJ's 26 June 2020 remarks, the agency expressed the importance of proceeding carefully, so as "not to discourage businesses, health care providers, and other companies from accessing in good faith the important resources that Congress made available in the CARES Act," providing that the Civil Division "will not pursue companies that made immaterial or inadvertent technical mistakes in processing paperwork, or that simply and honestly misunderstood the rules, terms and conditions, or certification requirements."[42]

Defense Strategies for Allegations Supported by Extrapolation

Providers that are unfortunately faced with an alleged overpayment supported by sampling and extrapolation have three main avenues for defense: (1) disputing the merits of the findings on the sample set, (2) examining the sampling and auditing processes, and (3) retaining a statistician to challenge the extrapolation process.

1. Disputing the Merits of the Sample Set

Whether an extrapolated overpayment by an auditor or an extrapolated damages estimate by the government in FCA litigation, the error rate or falsity rate on the sample set is the key to significantly changing the larger extrapolate findings across the sampling frame (i.e., the full time period of claims under review). The MPIM, Chapter 8, Section 4, provides detailed requirements for CMS contractors in developing an audit plan, a sample frame and set, and a sampling process that is intended to produce a randomly chosen sample set to objectively reflect the findings across the rest of the claims in the sampling frame.[43] The Office of Audit Services for HHS-OIG[44] uses a statistical software called RAT-STATS[45] and is supposed to conduct all auditing and extrapolations in accordance with Government Auditing Standards (GASAS) developed by Government Accountability Office (GAO).[46] Both the MPIM and GASAS standards are often used and applied by the HHS-OIG and DOJ in establishing a global fraud loss, and these same standards can be used to evaluate weaknesses in the auditing and sampling processes used to determine the findings in the sample set prior to the error rate or falsity rate being extrapolated. Further, as in *Loughren*[47] and *Agape*,[48] every effort to should be made in FCA litigation to advocate for a bellwether trial on the sample set before extrapolation, because the government's inability to prove falsity on even a small portion of the sample set can have an impact of reducing the overall damages by millions of dollars. Practically, challenges should be raised to the clinical qualifications of reviewers that made individual claims determinations, to the CMS coverage positions used as the standards for the services or device, and basis for denial is purely a difference of medical opinion.[49]

2. Challenging the Sampling and Auditing Process

Providers and counsel also should closely examine the sampling and auditing processes for weaknesses in the

government's presumptions from the claims data. Major considerations include conflicting reviews that should be excluded prior to drawing a sample set (i.e., has a portion of the sampling frame been reviewed in a prepayment audit by a MAC or by another CMS contract auditor with contrary findings), was the sample set genuinely random across the spectrum of services/supplies (i.e. were too many sample claims from high value claims selected in comparison to the percentage of high value claims within the sampling frame), or were reviewers provided an improper standard from which to make denials. Any one of these factors that can be shown to not have complied with MPIM and GASAS is grounds for invalidating the sample set.

3. Statistical Challenges

The value in retaining an expert witness to challenge the performance of the statistical extrapolation largely depends on the quality of the initial extrapolation process. If the GAO used RAT-STATS, considered the gold standard in statistical sampling and extrapolation, there may be little room to establish error. However, even RAT-STATS extrapolations are only as valid as the original determination on the sample set—establishing that a sample set or error rate is improper invalidates the extrapolation. If an auditor or relator has used statistical extrapolation to support an allegation, challenge the strata selection, confidence interval, and precision interval, as weaknesses in these most easily translate into something an adjudicator will understand—the divisions of review were improperly weighted (strata selection), the findings do not accurately reflect the whole frame (confidence interval), and the findings are not capable of accurate repetition (precision interval). Even HHS-OIG in August 2020 released a report chastising MACs and Qualified Independent Contractors for not properly evaluating extrapolations based on these primary issues.[50]

Providers Should Proactively Protect Themselves

Prior to an audit or investigation, providers should arm themselves with their own claims data to reduce risk and in preparation to withstand scrutiny. Providers should take full advantage of CMS programs that provide transparency for claims data analysis of their services in comparison to peers such as Comparative Billing Reports and Program for Evaluating Payment Patterns Electronic Reports.[51] Providers can take a deep dive into Public Use Files to analyze not only their own claims data but claims data of peers across the country.[52] Most importantly, once a provider has an understanding of their data performance according to CMS against peers, an internal analysis of the claims data should be run to determine if CMS reports are accurate or if there are valid explanations for being an outlier compared to peers.

Finally, the basics often prove to be the most useful. Routine review of coverage policies, internal documentation reviews, hiring an external auditor once a year, and documenting corrective action are critical. If an overpayment is discovered, make sure it is repaid timely and documented to stay off the radar.

Conclusion

In keeping with the anthem of change in 2020, regulators, prosecutors, and providers will be forced to increase their use and competency in data use and analysis as a means to evaluate the dramatic changes to reimbursement regulation. As relators and the government are anticipated to have far greater reliance on the presumptions that data analysis can raise for FCA allegations, providers must equally increase their sophistication and diligence in mining their own data for compliance. K&L Gates' health care fraud and payor-provider dispute teams continuously monitor developments in this arena to develop the most impactful defensive and proactive strategies available.

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[4] Id.

[5] DOJ, CIV. DIV., FRAUD STATISTICS – OVERVIEW OCTOBER 1, 1986 – SEPTEMBER 30, 2019 (Last visited Dec. 14, 2020), https://www.justice.gov/opa/press-release/file/1233201/download.

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[8] Id.

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[14] Factsheet, HHS-OIG, 2020 National Health Care Fraud TAKEDOWN (last visited Dec. 14, 2020), https://oig.hhs.gov/media/documents/2020HealthCareTakedown_FactSheet_9dtIhW4.pdf.

[15] DOJ, CRIM. DIV., FRAUD SECTION, FRAUD SECTION YEAR IN REVIEW 2017 (last visited Dec. 14, 2020), https://www.justice.gov/criminal-fraud/file/1026996/download; *see also* Press Release, DOJ, National Health Care Fraud Takedown Results in Charges Against 601 Individuals Responsible for Over $2 Billion in Fraud Losses (June 28, 2018), https://www.justice.gov/opa/pr/national-health-care-fraud-takedown-results-charges-against-601-individuals-responsible-over. (stating that DOJ has "taken historic new steps to go after fraudsters, including . . . leveraging the power of data analytics").

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[22] 604 F. Supp. 2d 259 (D. Mass. 2009).

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[24] 2015 WL 3903675 (D.S.C. June 25, 2015).

[25] 31 U.S.C. § 3730(e)(4).

[26] Schindler Elevator Corp. v. United States ex rel. Kirk, 563 U.S. 401, 407 (2011)..

[27] Medicare Program Integrity Manual [hereinafter MPIM], ch. 4.

[28] *Id.*

[29] *Id.*

[30] *Id.* § 4.2.

[31] *Id.*

[32] *Id.* § 4.2.2.1.

[33] 42 C.F.R. § 421.316(a); MPIM, ch. 4, § 4.2.2.2.

[34] MPIM, ch. 4, § 4.2.2.4.1; CMS Pub. 100-08, Transmittal 871 (Eff. Apr. 29, 2019), https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R871PI.pdf.

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[35] *Id.*

[36] *Id.*

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