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October 8, 2021

William N. Parham, III
Director
Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Paperwork Reduction Staff
Attention: CMS-10765
Room C4–26–05
7500 Security Boulevard
Baltimore, Maryland 21244–1850

#### SUBMITTED VIA REGULATIONS.GOV

# **Re:** Encompass Health Comments on the Notice of Collection of Information for a Review Choice Demonstration for Inpatient Rehabilitation Facility (IRF) Services (CMS–10765)

Dear Director Parham:

Encompass Health is pleased to provide the Centers for Medicare and Medicaid Services ("CMS") with the following comments on the Notice of Collection of Information for a Review Choice Demonstration for Inpatient Rehabilitation Facility Services ("IRF RCD"), published on September 8, 2021 (CMS–10765, 86 Fed. Reg. 50360) ("Notice"). Encompass Health is one of the nation's leading providers of post-acute care, operating 144 freestanding rehabilitation hospitals, 249 home health agencies, and 94 hospice locations. We provide post-acute and other critical services to thousands of Medicare beneficiaries every day and have an operating presence in 39 states and Puerto Rico.

In this paperwork reduction Notice, CMS announced an opportunity for the public to comment on its intention to collect information to support the potential implementation of an IRF RCD to enhance program integrity under the Medicare IRF benefit. In delivering important and necessary services to our patients, our rehabilitation hospitals ensure that they meet all Medicare requirements. As we indicated in comments earlier this year on the Agency's first paperwork reduction Notice for an IRF RCD, Encompass Health supports CMS' broader goals of reducing payment errors and ensuring correct payments for services.

We continue to be concerned that the approach contemplated in this paperwork reduction Notice and supporting documents is more likely to adversely impact patients' access to IRF care and services. It also will create substantial paperwork and operational burdens for clinical and administrative staff in freestanding rehabilitation hospitals and hospital-based inpatient rehabilitation units (also known as "IRFs"). IRF caregivers and other staff are already facing significant patient care and operational challenges associated with the COVID-19 pandemic, including in the state of Alabama where the demonstration is proposed to start.

Given stakeholders' significant concerns regarding patient access and provider burden, Encompass Health recommends that CMS not move forward with the IRF RCD. If CMS chooses to move forward with implementation, the Agency should address longstanding flaws in the Medicare Administrative Contractors' ("MACs") claims review process; employ safeguards to protect patients' access to the Medicare program's IRF benefit; instruct MACs to only deny

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claims based on noncompliance with regulatory requirements and not based on nonbinding guidance documents; significantly mitigate provider burden associated with the demonstration; and not implement the IRF RCD during the current public health emergency ("PHE").

# No Evidence of Fraud

We continue to object to CMS's justification for advancing this demonstration and its focus on the potential existence of "fraud" in the IRF sector, particularly since no evidence showing that existence has been referenced. As we indicated in our comments earlier this year on the initial paperwork reduction Notice, the Office of Inspector General ("OIG") report referenced by CMS in support of the IRF RCD does not even use or refer to this term in describing its analytical findings and policy recommendations.<sup>1</sup>

As we stated in our comments earlier this year, as recent court cases have articulated, claims that are denied on the basis of disagreements in clinical or medical judgment do not rise to the level of being "false" under the False Claims Act, so long as no objective falsity is present.<sup>2</sup> In other words, medical judgment disagreements do not necessarily indicate fraud. Yet, in the IRF RCD, CMS has cited the improper payment rate for IRF claims as an indicator of fraud without producing any evidence of actual fraud.

We respectfully reiterate that the Agency should not rely on the statutory authority at 42 U.S.C. 1395b-1(a)(1)(J) – which is explicitly intended for the pursuit of "fraud" – in order to justify the IRF RCD. Relying upon this statute as the basis for this demonstration exceeds CMS' statutory authority and has no legal support. Until CMS finds a different legal rationale for this demonstration or receives new authority from Congress, this demonstration should not begin.

Moreover, CMS' assertion that the Agency's "previous experience" has shown that there is "evidence of fraud and abuse" in IRFs simply does not comport with its historical policy and rule-making practices within the IRF PPS. In fact, the word "fraud" appears only one time in the preambles of the last 10 Proposed and Final Rules for the IRF PPS (FY 2022 through FY 2013, the latter of which was a Notice), in the Final Rule for FY 2020, when the Fraud and Abuse Act of 1986 was referenced. Were concerns about fraud and abuse as prevalent as CMS asserts in justifying the IRF RCD, IRF stakeholders surely would have been made aware of them over these past 10 years as part of the annual IRF PPS rule-making processes.

Finally, we question why IRF RCD is needed at all, since CMS has recently undertaken a revamped program, Uniform Program Integrity Contractors ("UPICs"), that will place considerable focus on fraud and abuse activities throughout the healthcare provider community.

<sup>&</sup>lt;sup>1</sup> See, HHS OFFICE OF INSPECTOR GENERAL, A-01-15-00500, Many Inpatient Rehabilitation Facility Stays Did Not Meet Medicare Coverage and Documentation Requirements (Sept. 2018), https://oig.hhs.gov/oas/reports/region1/11500500.asp.

<sup>&</sup>lt;sup>2</sup> See, <u>United States v. AseraCare, Inc.</u>, 938 F.3d 1278, 1297 (11th Cir. 2019) ("[A] reasonable difference of opinion among physicians reviewing medical documentation ex post is not sufficient on its own to suggest that those judgments—or any claims based on them—are false under the FCA.").

UPICs may "establish prepayment or postpayment reviews…where applicable," according to the Medicare Program Integrity Manual. The IRF RCD and the UPICs could overlap in their reviews, further burdening IRF providers.

## II. CMS Must Address the Major Disconnect Between Admitting Rehabilitation Physicians' Medical Judgments and MACs' Auditors and Reviewers Retrospective Reviews

In responding to comments received on the initial Notice for the IRF RCD, CMS asserts that "[t]he MACs are not substituting their judgment for the physician's, but ensuring that the documentation meets Medicare rules and clearly demonstrates the physician's reasons for ordering services." Respectfully, we disagree with this assertion. MACs routinely challenge the medical necessity determinations of treating rehabilitation physicians under their current auditing processes and it is likely that the same MACs under the IRF RCD will continue those challenges, likely at an even higher rate.

<u>A key concern we have with the pending IRF RCD program is the longstanding</u> <u>disconnect in CMS' medical review programs for IRF services between rehabilitation</u> <u>physicians who are required by Medicare regulations to evaluate each beneficiary</u> <u>presented to an IRF for potential admission and make an admission decision based on the</u> <u>applicable IRF coverage criteria and MACs' auditors and reviewers, the latter of whom</u> <u>evaluate and often deny those decisions based on a retrospective chart review without any</u> <u>interaction with either the patient or the admitting rehabilitation physician</u>. Fundamentally, this disconnect is rooted in differing interpretations (or notions of coverage that are not reflected in the applicable regulations) by auditors and reviewers of what satisfies Medicare's IRF coverage regulations, i.e., what is or is not "medically necessary," for a particular IRF patient.

These differing interpretations can pertain to any of Medicare's IRF coverage requirements, such as satisfaction of the intensity of therapy requirement, i.e., the so-called "Three Hour Rule,"; whether a patient was sufficiently stable at admission to participate in intensive therapy; whether a patient required multiple therapy disciplines; whether a patient required the supervision of a rehabilitation physician; whether a patient's records supported the need for an interdisciplinary team approach for her/his care; or whether a patient's preadmission screen was sufficiently constructed to justify the rehabilitation physician's decision to admit the patient.

We also note a troubling history of reviewers employing ad hoc rules and standards, or "rules of thumb," that have no basis in Medicare regulations, which continues to this day. For example, MAC auditors and reviewers look to see whether a patient's file contains snippets of information that can be used to assert that the patient "could have been treated in a less intensive setting," despite the 2010 IRF coverage regulations specifically not adopting this coverage standard.

Each of the IRF coverage requirements above requires considerable amounts of qualitative – and not quantitative – evaluation and examination by a rehabilitation physician

based on the unique characteristics and circumstances of the individual patient. As noted by one of the primary medical specialty societies representing medical rehabilitation physicians, the American Academy of Physical Medicine and Rehabilitation, in its comments submitted to CMS earlier this year on the initial paperwork reduction Notice for IRF RCD, Medicare's IRF coverage regulations "recognize[] a priori the physician's judgment when admitting a patient to an IRF and do [] not create black-and-white coverage rules that can be applied mechanically by auditors."

#### <u>In an environment involving a 100% audit of all IRF claims in a given state or</u> <u>MAC region, if this disconnect is not addressed and resolved before IRF RCD is</u> <u>implemented, it stands to result in a flood of "medical necessity"-based denials</u>. This flood will be administratively cumbersome and costly for CMS and healthcare providers; contribute to

will be administratively cumbersome and costly for CMS and healthcare providers; contribute to the backlog of cases already awaiting adjudication in the administrative appeals docket; will make attainment of a 90% affirmation rate difficult; and erode or eliminate patients' access to rehabilitative care they need and should receive. The result could be a much narrower Medicare IRF benefit in the future that excludes many patients with specialized rehabilitation needs. Many IRFs will be essentially discouraged or precluded from admitting categories of patients who will then be redirected to lower levels of care that may not be appropriate to meet their needs.

It is worth reiterating, moreover, that evidence of the disconnect between rehabilitation physicians admitting patients into IRFs and auditors and reviewers who subsequently deny IRF claims can be found in the high rate of overturn of these denials on appeal, and an IRF global settlement between CMS and the IRF field that restored payments of between 69% and 100% of payment amounts for all denied claims, except those associated from fraud. Further evidence of the arbitrariness of these reviews is the wide variations from year to year in the error rates for IRF care determined by the Comprehensive Error Rate Testing ("CERT") contractors.

We respectfully urge CMS to acknowledge the existence of this disconnect, and to proactively engage with IRFs and IRF stakeholders, particularly rehabilitation physicians, to meaningfully address it. If CMS chooses to move forward with IRF RCD in the future, it should incorporate ample safeguards into the program at its inception and throughout the demonstration's duration. Such safeguards should be designed to ensure that the clinical personnel who are auditing and reviewing IRF claims meet the same regulatory requirements CMS imposes on those responsible for admitting IRF patients and that these reviewers have demonstrable experience and skills in caring for IRF patients; that IRFs are not inundated with voluminous numbers of burdensome and costly denials, for which many of them will have to wait many months or years to resolve through the administrative appeals process; and that patients' access to IRF care will not be improperly eroded or eliminated. Should CMS address the flaws in the IRF claims review process, both in the RCD and more broadly in other IRF review programs, the result would be a vastly improved error rate and improved access and quality of care for beneficiaries.

As we noted in our comments responding to the initial paperwork reduction Notice for IRF RCD earlier this year, in most instances rehabilitation physicians who admit patients into IRFs are independent contractor practitioners with no employment or financial relationship with the IRF in which they admit patients. Oftentimes, decisions by the MAC or CERT contractor to

overrule the judgment and experience of the admitting rehabilitation physician at the IRF are made by non-physicians or physicians who have little or no experience in medical rehabilitation or in caring for IRF patients and lack a sufficient understanding of the IRF coverage requirements.

It is a notable inconsistency that CMS' own rules for IRF coverage and benefits place such a high value on the judgment, experience, and training of rehabilitation physicians but CMS' oversight process easily disregards it based on reviews by MAC and CERT contractor staff who lack such training and experience. In addition, due to their lack of familiarity with medical rehabilitation and IRF care, these contractor review staff often apply novel or ad hoc standards and review criteria that are inconsistent with established Medicare regulations. <u>To</u> <u>help alleviate the effects of the disconnect between rehabilitation physicians who admit and</u> <u>treat IRF patients and MACs' IRF auditors and reviewers, we respectfully recommend the</u> <u>following for the IRF RCD if CMS chooses to implement it</u>:

- Audit and review activities of IRF claims under the RCD should be carried out by rehabilitation physicians with demonstrated experience and training in caring for IRF patients; denials rendered by non-rehabilitation physician auditors or reviewers should be reviewed and approved by a rehabilitation physician.
- CMS should establish a Medical Rehabilitation Advisory Board comprised of practicing rehabilitation physicians with demonstrated training and experience caring for IRF patients and CMS personnel, including personnel who are charged with developing and administering the IRF RCD; developing Medicare's IRF coverage regulations and policies; and overseeing CMS' contractual relationships with the MACs. The Board should meet at least annually and function to provide, among other purposes, advice and input on the clinical interpretation of medical necessity for IRF services and interpretation of Medicare's IRF coverage regulations and policies.

## **III.** Training and Education of MACs' IRF Auditors and Reviewers

As we noted in our February comments and reiterate here, for years IRF stakeholders have expressed concerns to CMS regarding Medicare contractors' lack of training and expertise with specialized rehabilitation care and Medicare's IRF coverage requirements. In responding to comments on the initial paperwork reduction Notice for IRF RCD, CMS asserts that "[r]eviewers will follow the same review guidelines as they currently do" and the "MAC reviewers will undergo training to ensure consistency prior to beginning the reviews." Respectfully, IRF stakeholders find little comfort in either of these assertions. In fact, the prospect of MACs' IRF auditors and reviewers following the same review guidelines they currently follow suggests the IRF RCD will produce a rash of new denials and raise continuing medical necessity disputes between CMS contractors and IRF admitting physicians.

The education and training of MAC auditors and reviewers pertaining to Medicare's IRF coverage regulations and policies historically has been a "black-box" process for IRFs which has

contributed to the disconnect discussed above. CMS should take proactive steps to avoid status quo IRF audits and reviews by adopting appropriate safeguards that are built into the IRF RCD. Such safeguards should be designed to promote consistency, transparency and open lines of communication, and mutual expectations of all parties – auditors and those being audited – as part of the training and education component of the IRF RCD demonstration.

It is a near certainty that MACs do not have sufficient staff to handle the substantial increase in IRF RCD audit and review activities, so they will have to hire more employees or contract with third parties to meet this considerable workload increase. The fact that CMS estimates the RCD program will cost the federal government \$114 million over five years is strong evidence that their contractors will have to dramatically increase IRF auditing staff. Education and training of these new (and existing) personnel will be critically important. We respectfully recommend that the education and training component for IRF RCD be comprised of at least the following safeguards:

- Training of IRF RCD non-rehabilitation physician audit and review personnel should be conducted by rehabilitation physicians with actual, recent experience in caring for IRF patients.
- All IRF training materials, including case or patient examples, utilized in the education and training activities to demonstrate what is or is not "medically necessary" under Medicare's IRF coverage requirements should be publicly disclosed to IRF stakeholders subject to the demonstration, including patient organizations.
- CMS and MACs should develop education and training materials and guidelines for IRF RCD that comply with the regulatory coverage requirements and reflect feedback and input from the Medical Rehabilitation Advisory Board, recommended above; these materials and guidelines should be publicly disclosed and shared with all IRF stakeholders subject to the demonstration prior to its implementation.
- All MACs undertaking audits and reviews of IRFs under the RCD should be required to establish an IRF RCD Advisory Council or similar type of body prior to implementation. The Council should be comprised of IRF medical directors and rehabilitation physicians who are actively practicing in IRFs located in a state or MAC region in which the IRF RCD is to be implemented. MACs should be required to confer with and receive input from members of the Council on a regular, recurring basis, at least two months prior to the demonstration's implementation in the state or MAC region and at least quarterly thereafter. These meetings should facilitate discussion and dialogue about the demonstration, including how Medicare's IRF coverage regulations and policies are being interpreted and applied by IRFs and the MAC reviewers throughout the course of the demonstration.

#### IV. No Denials Should be Based on the MBPM Alone

With respect to the standard of review that CMS will instruct its MACs to use with RCD IRF reviews, we are particularly concerned that the Medicare manual provisions (specifically from the Medicare Benefit Policy Manual ("MBPM"), CMS Pub. 100-02, Chapter 1) will be used by MACs to justify denials of IRF claims. Such denials frequently form the basis for some of the most foundational disagreements between Medicare contractors and the IRF field as to what constitutes the appropriate coverage criteria for IRF admissions. This practice is wholly inconsistent with the U.S. Supreme Court's ruling in *Azar v. Allina Health Services* that all substantive payment standards must be promulgated through regulations.<sup>3</sup>

In *Allina*, the Court held that the Medicare statute, at 42 U.S.C. § 1395hh(a)(2), imposes rulemaking obligations upon CMS that exceed those of the Administrative Procedure Act ("APA"). The Medicare statute does not incorporate the APA's interpretive rule exemption from notice and comment rulemaking.<sup>4</sup> Therefore, if an interpretive rule or statement of policy establishes or changes a substantive legal standard governing payment for services, it must be promulgated by notice and comment rulemaking.<sup>5</sup> The Court's holding applies to Medicare manuals, including the MBPM.<sup>6</sup>

While the Department of Health and Human Services ostensibly complies with the holding of *Allina* through its regulation at 45 C.F.R. § 1.6, which prohibits the denial of a provider's claim solely based on guidance in the MBPM, we note that the Statements of Work ("SOWs") currently in effect for the MAC jurisdictions identified under the proposal specifically require the contractors to adhere to and apply the provisions of Medicare manuals as "Medicare policy requirements."<sup>7</sup> The experience of IRFs during past audits reflects that the MACs adhere closely to the requirements laid out in the Statements of Work to which they are a contracting party, even when the coverage requirements reflected in the manual provisions are not otherwise set forth as properly binding coverage criteria in federal regulation.

For example, many IRFs have had claims denied when the MAC determines that the patient's plan of care omits details about the anticipated interventions (including expected intensity, frequency, and duration of therapies required) or anticipated functional outcomes; however, nowhere in the regulation at 42 C.F.R. § 412.622 are any such requirements specified. Instead, the requirements of the regulation establish that the individualized overall plan of care must be developed by a rehabilitation physician with input from the interdisciplinary team within four days of the patient's admission to the IRF.<sup>8</sup> The remaining standards applied by the MACs

<sup>&</sup>lt;sup>3</sup> See 139 S.Ct. 1804 (2019).

<sup>&</sup>lt;sup>4</sup> *Id.* at 1811.

<sup>&</sup>lt;sup>5</sup> Id.

<sup>&</sup>lt;sup>6</sup> See id. at 1816; see also id. at 1823 (Bryer, J., dissenting) (identifying the MBPM as among the manuals subject to the Court's holding).

<sup>&</sup>lt;sup>7</sup> See, e.g., 'Part A and Part B Medicare Administrative Contractor Statement of Work: Jurisdiction E,' Attachment J.1.,

Section C.2.3. – Medicare Manuals (last revised 02/15/2019). The SOWs for the other four impacted jurisdictions contain similar or identical language under the same section heading.

<sup>&</sup>lt;sup>8</sup> 42 C.F.R. § 412.622(a)(4)(ii).

exist only in the MBPM and, under *Allina*, are unenforceable. Denying claims solely for reasons contained in the MBPM that are not otherwise stated in the regulations is erroneous.

Moreover, in the Final Rule for the FY 2021 IRF PPS, CMS codified a number of MBPM provisions into the IRF coverage regulations but opted to not codify some provisions, including a patient's expected frequency and duration of treatment in the IRF; any anticipated post-discharge treatments; and other information relevant to the patient's care needs. It has been our recent experience in the context of Medicare Advantage medical audit and chart reviews that contractors overlook the fact that these provisions were not codified into the regulations in the FY 2020 Final Rule, but since the provisions still remain in the MBPM they are still being utilized as bases to deny claims. We are concerned that MACs' auditors and reviewers will similarly overlook that these provisions are not part of the IRF coverage regulations yet still improperly utilize them as bases to deny claims under IRF RCD.

IRFs have every reason to believe that they will see many claims denied under the RCD for similar unsupportable reasons, resulting in needless administrative burden, the need to appeal each one of these claims, and, most egregiously, delayed or withheld medically necessary patient care. The MBPM can certainly continue to serve as guidance for industry best practices, to be referred to by IRFs and CMS alike, but the contractors must be bound only by the regulatory requirements and should be prohibited from using guidance to make binding decisions on payment or coverage of IRF claims. Therefore, if CMS insists on proceeding with the RCD, it must issue revised SOWs or other explicit and binding instructions to the impacted MACs that clearly require that denials under the RCD may <u>only</u> be based upon provisions contained in the regulations.

## V. Monitoring The IRF RCD

In its response to comments on the initial paperwork reduction Notice for IRF RCD, CMS asserts that "[b]oth the MAC and CMS will monitor the reviewers' accuracy throughout the demonstration and CMS staff will conduct reviews on a selection of requests/claims to ensure the MAC decisions are accurate and consistent across reviewers. Additionally, these reviews will be subject to accuracy reviews by the designated contractor."

We appreciate CMS committing to monitor the RCD for accuracy and consistency, as both are critically important in order to avoid improper claim denials; a flood of appeals and the administrative burdens and costs associated with them; and most importantly, an erosion or even elimination of patients' access to specialized rehabilitative care provided by IRFs that they need and should receive. However, it is not at all clear what these monitoring activities will be comprised of, how the data and information derived from them will be utilized, and what input, if any, IRFs will have in the monitoring process. <u>We respectfully recommend that the</u> **monitoring component for IRF RCD be comprised of at least the following safeguards**:

> MACs and their audit and review personnel should be required to meet with and discuss any concerns or problems with the IRF RCD with providers that request such meetings. For example, auditors and reviewers denying IRF claims for

"medical necessity" reasons, e.g., the patient did not need intensive therapy, or the patient was not sufficiently stable at admission, should be required to engage in dialogue with the admitting rehabilitation physician, if the latter requests it, in order to discuss their perspectives. Such a dialogue could help clarify document deficiencies, clarify clinical details, help set mutual expectations, and avoid needless denials. There is precedent for this safeguard, the "discussion period" under the permanent Recovery Audit Contractor (RAC) program.

- There should be a formal process built into RCD from its inception and maintained throughout the duration of the demonstration program that enables IRFs to proactively bring forward to CMS and the MACs – such as by an "ombudsperson" or similar type of role within CMS and the MACs – any concerns with RCD, whether procedural or substantive in nature, involving specific cases, practices, or policies. This process should include an opportunity for actual collective dialogue and exchange between IRFs, CMS, and the MACs.
- Data and information derived from monitoring activities should be regularly shared with providers in the states where IRF RCD is implemented in order to compare and evaluate consistency across the MACs. For example, IRFs should be made aware of the number of claims being denied under RCD, in its state and from other states where RCD is in effect, as well as the types of cases being denied, e.g., by case mix group ("CMG") and comorbidity tier, and the reasons for denial.

# In addition to the recommended safeguards above, we also recommend the <u>following</u>:

- We appreciate CMS' recognition that a 10-day turnaround time for second and subsequent submissions of pre-claim reviews was far too long for the MAC to respond. However, we respectfully assert that a 5-business day turnaround time for such submissions is still too long. IRFs admit and treat patients 7 days per week and the average length of stay is approximately 13 days. MACs administering the RCD program should be required to respond to pre-claim denials within 24 hours of a resubmission and should be available during weekends and holidays as well.
- It is not clear how the MACs will be able to receive and respond to electronic submissions – more information and details are needed in order to better understand this aspect of the process.
- It is not clear whether all claims subjected to the IRF RCD, including claims submitted on a post-payment basis, will be subjected to additional audit and review activities after an initial determination has been approved. CMS should clarify that no claims subjected to RCD regardless of whether they are pre-claim or post-payment will be subsequently subjected to additional audit or review by the MACs, RACs, SMRCs, UPIC, or other CMS auditors.

- We are concerned that RCD will likely result in an abnormally high number of claim denials, thereby contributing to the 80,000+ backlog of cases currently awaiting adjudication in the ALJ appeals process. Such a large number of IRF RCD denials could create a backlog similar to the one created by the RAC audits several years ago. CMS should account for this possibility by building additional efficiencies and resources into the MAC and ALJ levels of review in order to ensure that providers' appeals are heard in accordance with statutory requirements.
- RCD should be applied on a prospective-only basis; the only claims to be reviewed under the program should be those with dates of service following the demonstration's implementation involving IRFs that have designated their chosen track.

#### VI. CMS Should Not Implement the IRF RCD During the Current COVID-19 PHE

Given the provider burdens and administrative and technical complexities that will be involved with the IRF RCD as outlined by CMS in the paperwork reduction Notice and supporting documents, the demonstration program should be delayed until a reasonable period of time following the end of the PHE and the ongoing effects of COVID-19 on general acute care hospitals and post-acute care providers have substantially subsided. The demonstration will create challenges for patients, MACs, and providers, including clinical staff who will be directed away from patient care to address document collection and patient file review required by IRF-RCD. CMS assumes, as reflected in the Supporting Statement Part A document for the IRF RCD, that only "clerical staff" will be involved in the IRF RCD documentation process and that the work associated with it amounts to "office clerical activities." Respectfully, these assumptions are incorrect.

In addition, initiating the demonstration in Alabama will place substantial burden on a state health system that is already struggling under the weight of the pandemic. Alabama has been challenged particularly hard by COVID-19 in recent months, and CMS should not subject its IRFs to a 100% audit of all claims. The recent mortality rate for COVID-19 in Alabama was 275 deaths per 100,000 people during the course of the pandemic, making it the fifth highest rate in the U.S. after Mississippi, New Jersey, Louisiana, and New York.

Finally, we note that it will be very difficult, if not impossible, for the MACs to implement the IRF RCD during the PHE given the ongoing application of various waivers and flexibilities involving the IRF coverage regulations. Coverage-related regulations that are either non-applicable or applicable with certain caveats during the pandemic will directly impact the process for "medical necessity" determinations. For these reasons, if CMS chooses to move forward with the IRF RCD, we recommend that CMS not implement the program until after the PHE has expired and the effects of COVID-19 on healthcare providers' operations have subsided.

#### VII. Conclusion

Encompass Health appreciates the opportunity to comment on CMS' Notice for the IRF RCD paperwork reduction requirement. We support CMS' efforts to be a prudent steward of Medicare dollars and its efforts to enhance program integrity in the program. However, given the significant concerns outlined in this letter regarding patient access and provider burden, we recommend that CMS not move forward with the IRF RCD. CMS can instead make improvements to its medical review approach for IRFs to address longstanding flaws which will benefit both patients and the Medicare program.

If CMS chooses to move forward with IRF RCD, the Agency should address these longstanding flaws in the MACs' IRF claims review processes; employ safeguards to protect patient access to the IRF benefit; significantly mitigate provider burden associated with the demonstration; and not implement the IRF RCD during the present PHE and until COVID-19's impacts on healthcare providers have subsided. It is critical that programs such as the IRF RCD, if implemented, are designed and administered by CMS in a way that maintains patients' access to care and services that they need and to which they are entitled as Medicare beneficiaries. Please feel free to contact me if there are any questions about this letter at (202) 448-1649 or justin.hunter@encompasshealth.com.

Sincerely yours,

Justin R. Auster

Justin R. Hunter Senior Vice President Public Policy, Legislation & Regulations Encompass Health

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