December 6, 2021

Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244-8016  
Submitted via https://www.regulations.gov

Re: Requirements Related to Surprise Billing; Part II; CMS–9908–IFC; RIN 0938–AU62

Dear Administrator Brooks-LaSure:

The Society of Nuclear Medicine and Molecular Imaging (SNMMI) appreciates the opportunity to comment on the Requirements Related to Surprise Billing; Part II interim final rules with comment period (“IFCs Part II”) implementing provisions of the No Surprises Act (“Act”) issued by the U.S. Department of Health and Human Services (HHS), the U.S. Department of Labor, and the U.S. Department of the Treasury (collectively, the “Departments”).¹ SNMMI’s more than 15,000 members set the standard for molecular imaging and nuclear medicine practice by creating guidelines, sharing information through journals and meetings, and leading advocacy on key issues that affect molecular imaging and therapy, research, and practice.

SNMMI strongly supports the goals of the No Surprises Act, including protecting patients from surprise medical bills, improving the availability of affordable, high-quality, in-network care, and developing a fair and impartial process for resolving provider-insurer payment disputes.

Consistent with accomplishing these goals, we recommend that the Departments provide certain important clarifications and/or modifications to the interim final rules (IFCs), as appropriate, for the following issues:

1) The Departments should issue subregulatory guidance clarifying the scope of items and services deemed to be furnished “with respect to a visit,” particularly as these rules apply to out-of-network ancillary services that are ordered during a visit but furnished after an applicable in-network facility visit. Specifically, the Departments should clarify that ancillary services merely ordered or referred during an in-network “visit” but not furnished

until a separately scheduled period of care occurring at a later point in time are not within the scope of the original “visit.”

2) The Departments should establish rules to enhance the transparency and oversight around an insurer’s calculation of the “qualifying payment amount” (QPA) to ensure that it appropriately reflects the in-network market rate for the same or similar item or service.

3) The Departments should amend the rules regarding the independent dispute resolution (“IDR”) process to appropriately reflect Congress’s intent that IDR entities consider all relevant considerations equally when selecting between the two parties’ offers, rather than presuming that the QPA reflects the appropriate out-of-network rate.

Our detailed recommendations follow below.

I. Clarifications are Needed Regarding the Scope of a Visit with Respect to Ancillary Services

To understand and implement the No Surprises Act and the Departments’ IFCs, patients, providers, and insurers need additional guidance clarifying the scope of a “visit” in the case of ancillary services furnished pursuant to an order or referral received by a patient during a visit to an in-network facility. Under the Act and the IFCs, items and services can result in “surprise bills” when they are “furnished to [an insured patient] . . . by a nonparticipating provider . . . with respect to a visit at a participating health care facility” (unless the provider has satisfied notice and consent criteria). As it relates to ancillary services ordered or referred during care provided at an in-network facility, the “with respect to a visit” language is vague and requires additional clarification to specify clearly when subsequently furnished items and services are no longer “with respect to” a prior visit.

In particular, SNMMI’s members provide patients with diagnostic imaging services, referred to in the Act the implementing IFCs as a type of “ancillary service,” pursuant to a practitioner order or referral. As a general matter, imaging services include both a technical component (e.g., performing the imaging scan including the instrumentation, technical personnel, facility and radiopharmaceuticals) and a professional component (e.g., planning and interpreting the imaging scan). Typically, a patient will receive an order for nuclear or molecular imaging services, which their practitioner believes will enable him or her to diagnose or inform treatment of the patient’s disease. The patient may, for example, receive this order during an appointment with that practitioner. In some cases, the patient may be able to receive the technical component of imaging services on the same date as the “visit” as a part of the original appointment. In other words, after the practitioner orders an imaging examination, the patient may be able to receive the ordered scan at the same facility of their appointment, perhaps by walking down the hall of the facility to the site where imaging services are performed. However, in many cases, the patient may not receive any component of the imaging services during their original appointment, or even at the same

2 45 C.F.R § 149.120(b) (emphasis added); see also 42 U.S.C. § 300gg-132(a).

3 Usually, the professional component of the service, wherein a practitioner interprets the imaging scan, would then occur at a later point in time. As discussed below, SNMMI presumes the relevant facility for the purposes of assessing whether the professional component of imaging services triggers a surprise bill is the facility in which the imaging scan/technical component was performed. SNMMI also seeks clarification in this regard.
facility. In these cases, the patient may be required to reach out to the imaging provider and schedule a separate appointment for the ordered services. Then the patient would travel to the location of the imaging services provider for the ordered examination. In the latter scenario, the imaging services could be performed days or weeks after the initial “visit” in which those services were ordered. While SNMMI believes the first example describes ancillary services that are provided “with respect to” the patient’s original “visit,” the IFCs do not clearly describe how to consider ancillary services that are ordered during an original “visit” but are furnished during a separately-scheduled period of care occurring at a later point in time.

After a careful review of the Act, the IFCs, the Departments’ preamble discussions, and the animating purposes behind surprise billing protections, SNMMI believes subsequently furnished items and services, such as imaging services ordered during an in-network visit, are not “furnished . . . with respect to” the initial visit when they are performed during a separately scheduled period of care occurring at a later point in time. SNMMI urges the departments promptly to issue subregulatory guidance to clarify this important issue: ancillary services merely ordered or referred during an in-network “visit” but eventually furnished during a separately scheduled appointment at a later point in time are not within the scope of the original “visit” and therefore cannot trigger a related “surprise bill” under the No Surprises IFCs.

Although clarity is needed, SNMMI believes the Act and IFCs support this understanding that a “visit” does not extend to care provided at a later point in time, for example, after the patient has left the in-network facility. In particular, both the Act and the IFCs provide that:

Visit, with respect to items and services furnished to an individual at a health care facility, includes, in addition to items and services furnished by a provider at the facility, equipment and devices, telemedicine services, imaging services, laboratory services, and preoperative and postoperative services, regardless of whether the provider furnishing such items or services is at the facility.5

This definition indicates that a “visit” includes the items and services furnished while the patient is physically located “at” the in-network facility. Even though the provider does not need to be “at” the in-network facility, the visit definition requires that the patient must be. Therefore, items or services separately furnished to a patient after the patient has left the facility do not fall within the statutory limitations defining the scope of a “visit.”6

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4 By contrast to the former example, this scenario involves a patient who is furnished the technical and professional component of an imaging service at a later point in time following the appointment in which the service was ordered and at a different facility. SNMMI also seeks clarification regarding the scope of a “visit” when a patient receives the imaging services at a later point in time following the appointment in which the service was ordered at the same location of the original visit.
5 45 C.F.R. § 149.30 (emphasis added).
6 In addition to the scenarios discussed above, a patient’s care might also involve imaging services that were ordered by a practitioner but are unaffiliated with any given appointment or scheduled “visit” at a facility in which care was provided to a patient. For instance, a practitioner might order imaging services after reviewing certain other diagnostic test results without otherwise treating the patient in person at a facility. SNMMI assumes that such imaging services would not trigger a surprise bill as it relates to the facility of the ordering practitioner because they will not have been performed “with respect to” any patient “visit.” SNMMI also seeks clarification in this regard.
The IFCs Part I preamble provides examples highlighting the temporal element of this statutory limitation. In particular, these examples emphasize that items and services must be furnished during the “visit” to be considered a surprise bill.

- **Example 1**: “[I]f a sample is collected during an individual’s hospital visit and sent to an off-site laboratory, the laboratory services would be considered to be part of the individual’s visit to a participating health care facility, if laboratory services are covered by the plan or coverage.”

- **Example 2**: “[I]f an individual receives a consultation with a specialist via telemedicine during a visit to a participating hospital, those telemedicine services would be considered part of the individual’s visit to a participating health care facility.”

These examples underline that items and services are only “considered to be part of the patient’s visit to an in-network facility” when those items or services are furnished during the period of care that occurs at the in-network facility.

To delineate the items and services considered to be furnished “during” a patient’s in-network visit, the Departments should rely on the same distinction they highlighted in the context of good-faith estimates. There, the Departments designate the items and services to be included in a good-faith estimate based on those items or services “reasonably expected to be provided” at the facility in connection with a patient’s scheduled appointment for a “period of care.” Specifically, the IFCs Part II provide that a “period of care” means:

“[T]he day or multiple days during which the good faith estimate for a scheduled or requested item or service (or set of scheduled or requested items or services) are furnished or are anticipated to be furnished, regardless of whether the convening provider, convening facility, co-providers, or co-facilities are furnishing such items or services, including the period of time during which any facility equipment and devices, telemedicine services, imaging services, laboratory services, and preoperative and postoperative services that would not be scheduled separately by the individual, are furnished.”

In other words, a period of care includes all of the items and services that a patient receives at a facility when they schedule an appointment for care with a provider. According to the IFCs Part II, a period of care can include related imaging services (even if furnished by a provider other than the primary provider with whom the patient schedules the appointment), but only those “that would not be scheduled separately by the individual.” In short, a period of care is distinguished

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9 45 C.F.R. § 149.610(a)(2)(vi), (c)(1)(iii).
10 45 C.F.R. § 149.610(a)(2)(x).
11 See 45 C.F.R. § 149.610(a)(2)(x).
based on the items and services that are part of the patient’s scheduled appointment. Items and services that require a distinct appointment are not within the same “episode of care.” 12

The Departments should adopt this same framework to define clearly the scope of a “visit.” Namely, in alignment with the “period of care” definition, the items and services that are part of a visit should include only the items or services provided to the patient during the period of time at which the patient is at the facility (i.e., on that date or, if the patient is continuously at the facility, until the patient leaves the facility), either as a result of a scheduled appointment or an emergency stay. If items or services are provided during a separately-scheduled appointment (e.g., occurring at a later period in time), that separate scheduling triggers a separate “visit.” 13 In that case, the location of the separate visit where the patient receives care is assessed to determine whether items or services provided during that visit result in a surprise bill, and the network status of the facility of the prior visit is no longer relevant. This clarification creates a clear standard to identify the scope of a “visit” that aligns with both the language of the Act and IFCs defining the term, as well as the information that patients will receive as a part of a good-faith estimate.

This clarification also would be consistent with the animating purposes behind the Act, which according to both the Departments and lawmakers is to protect patients from unexpected medical bills. 14 Patients might reasonably expect all items and services that they receive during a single “visit” at a facility to be in-network with their insurance if that facility also is in-network. However, it may not be reasonable for that patient to assume that all services ordered as a result of that original visit also are in-network, particularly where the patient must make a separate appointment at a later point in time, at a separate facility and with a separate provider. In that scenario, the patient would have an appropriate opportunity to determine the network status of the ancillary services provider or select another provider based on their insurance network. Without clear parameters defining the scope of a visit, surprise billing protections could become detached from the Act’s initial purpose and extend without limitation to situations not intended by Congress.

Therefore, for the above reasons, SNMMI urges the Departments to issue subregulatory guidance clarifying that ancillary services merely ordered or referred during an in-network “visit” but eventually furnished during a separately-scheduled appointment (i.e., period of care) at a later point in time are not within the scope of the original “visit” and therefore cannot trigger a related “surprise bill” under the No Surprises IFCs.

12 See 45 C.F.R. § 149.610(c)(1)(vi) (referring to separately-scheduled items or services as occurring prior to or following a particular “period of care”); see also 86 Fed. Reg. at 56,019. Infeed, for items and services that require separate scheduling by the patient, the IFCs Part II instruct providers to list the items or services separately on the good faith estimate and clearly disclaim that expected charge information is not required to be included in the good faith estimate “as that information will be provided in separate good faith estimates upon scheduling or upon request of such items or services.” 45 C.F.R. § 149.610(c)(1)(vi).

13 SNMMI also encourages CMS to clarify that this same understanding is appropriate in circumstances where a patient may seek out a second practitioner to interpret the patient’s imaging scan as a second opinion. In this case, the practitioner would perform the professional component of the imaging services at the request of the patient. SNMMI encourages CMS to clarify that, for the purposes of assessing whether surprises billing protections apply, this subsequent request for services involves a separate scheduling that also would trigger a separate “visit.”

In addition to this key clarification, SNMMI also urges the Departments to issue subregulatory
guidance addressing the following two points:

- First, as discussed above, imaging services typically include both a technical component
  (e.g., performing the imaging scan) and a professional component (e.g., interpreting the
  imaging scan). Where the technical component of imaging services (i.e., performing the
  imaging scan) is performed during a separately scheduled appointment, and thus involves
  a distinct “visit” from the period of care during which the imaging service was ordered,
  SNMMI presumes that the relevant facility for the purposes of assessing whether the
  professional component of imaging services triggers a surprise bill is the facility in which
  the imaging scan/technical component was performed. In this case, SNMMI understands
  that the professional component of the imaging services would be furnished “with respect
  to” the patient’s visit at the facility in which the scan was physically performed on the
  patient (regardless of whether the professional reading the scan is “at” the facility). In other
  words, the network status of the facility where the test was ordered is not relevant in
  establishing whether a surprise bill occurred.

- Second, also referenced above, SNMMI envisions a scenario in which a patient receives
  imaging services ordered by a practitioner that are unaffiliated with any given appointment
  in which care was provided to a patient. For instance, a practitioner might order imaging
  services after reviewing certain other diagnostic test results without otherwise treating the
  patient in person. SNMMI assumes that such imaging services would not trigger a surprise
  bill as it relates to the facility of the ordering practitioner because they will not have been
  performed “with respect to” any patient “visit.”

II. The No Surprises Act Regime and the Adequacy of Provider Payments More
Generally Require Enhanced Transparency and Oversight of QPA Calculations

The QPA under the Act is intended to reflect the “median of the contracted rates recognized [by
insurance] for the same or similar item or service.”15 Confidence in the No Surprises Act requires
the QPA correctly and justifiably reflect the amount insurers reimburse for the same or similar
contracted item or service. The QPA has significant implications under the Act and the IFCs
because, in the case of a surprise bill, it directly impacts a patient’s cost-sharing amount, out-of-
network payment determinations during the IDR process, and equally important, is very likely to
affect payment rates more generally.16 Recognizing its importance, the Departments described
their view that “the statute sets out detailed rules for calculating the QPA, suggesting that an
accurate and clear calculation of the QPA is integral” to the No Surprises Act framework.17 For
these reasons, the IFCs require insurers to account for provider type, procedure complexity, and
patient acuity, and billing code modifiers when calculating the QPA to help ensure that the QPA

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16 Exemplifying that reliance on the QPA as a benchmark influences provider reimbursement downward see e.g.,
17 86 Fed. Reg. at 55,996 (emphasis added).
accurately reflects the in-network payment rate for the actual item or service provided.\textsuperscript{18} The Departments again highlighted the importance of an accurate QPA in the IFCs Part II preamble, indicating their belief that the calculated metric will represent a “reasonable” out-of-network rate under most circumstances.\textsuperscript{19} The importance of the QPA cannot be understated; and likewise, its correct calculation is essential to a fair and efficient No Surprises regime that is rooted in precision and accountability.

Considering the importance of the QPA, SNMMI encourages the Departments to take all necessary steps to ensure that the QPA is calculated accurately. Despite the Department’s acknowledgement that a correctly calculated QPA is fundamental to the IDR process, the assumption that the QPA will be correct without transparency and further oversight into the calculation methods is worrisome.

The QPA is arguably the most integral piece of the No Surprises Act, and its influence over IDR entities’ determination of the appropriate out-of-network payment amounts incentivizes insurers to calculate the QPA as low as possible. Not only would this undermine the No Surprises regime, it could have a ripple effect through the healthcare marketplace. Specifically, if insurers are able to advance QPAs that are lower than actual market rates, they may be disincentivized from entering into network contracts, resulting in reduced patient access to in-network providers and greater exposure to out-of-network cost-sharing rates in circumstances where the No Surprises regime does not apply.

At the same time, as currently drafted, the IFCs do not permit either providers or IDR entities to obtain sufficient information to evaluate the accuracy of the calculation or provide sufficient mechanisms to challenge or report miscalculations. Therefore, it is critical the Departments establish safeguards to promote greater oversight and increased transparency around the QPA calculation. SNMMI urges the Departments to issue sub-regulatory guidance and/or modify its existing policies to incorporate the following safeguards:

- **Certified IDR entities should be required to determine whether the QPA was calculated appropriately.** As currently codified in the IFCs, “[t]he certified IDR entity must select the offer closest to the qualifying payment amount unless the certified IDR entity determines that credible information submitted by either party under paragraph (c)(4)(i) clearly demonstrates that the qualifying payment amount is materially different from the appropriate out-of-network rate.”\textsuperscript{20} The Departments make clear, however, that a certified IDR entity does not have a role in verifying that the insurer has properly calculated the QPA in the first instance.\textsuperscript{21} The Departments only encourage the certified IDR entity to submit a complaint against the insurer or notify the appropriate state or federal authority of their suspicion that “the QPA has not been calculated in accordance with the [regulatory] requirements.”\textsuperscript{22} Because a correctly calculated QPA is so vitally important to the IDR process, SNMMI implores the Departments to require the certified IDR entity to confirm

\textsuperscript{18} 86 Fed. Reg. at 55,997
\textsuperscript{19} 6 Fed. Reg. at 55,996 (“Generally, the QPA should reflect standard market rates arrived at through typical contract negotiations and should therefore be a reasonable out-of-network rate under most circumstances.”)
\textsuperscript{20} 45 CFR 149.510(c)(4)(ii)(A) (emphasis added).
\textsuperscript{21} 86 Fed. Reg. at 55,996.
\textsuperscript{22} 86 Fed. Reg. at 55,996 n.31.
the accuracy of the QPA calculation as part of the IDR process when this issue is raised by
the provider. This additional safeguard will not only support appropriate calculations of the
QPA, consistent with regulatory requirements, but will help inform IDR entities’
examination of whether “credible information [. . .]clearly demonstrates that the QPA is
materially different from the appropriate out-of-network rate.”23 Moreover, without
additional information about how an insurer calculated the QPA, it is unclear how any
provider could appropriately challenge or IDR entity determine whether the QPA does not
accurately reflect the value of the item or service provided.24

- The Departments should require plans to disclose enough information about the QPA
calculation to facilitate validation by the provider or IDR entity that the calculation
conforms with the requirements of the IFCs. SNMMI commends the Department’s goal of
“transparency regarding how the QPA was determined.”25 However, the requirements
outlined by the IFCs Part I only require limited information sharing including the calculated
QPA, certification statements indicating it was calculated in compliance with the law, and
other limited information upon the provider’s request. SNMMI urges the Departments to
require insurers to provide affirmative information regarding the service code-modifier
combination used to calculate the QPA, the number of contracted rates relied upon by the
insurer, the geographic region used to calculate the QPA, as well as the additional
information described in 45 C.F.R. § 149.140(d), regardless of whether it is requested by
the provider. These crucial disclosure requirements will allow providers the necessary
insight to determine whether the QPA was calculated in an allowable manner and challenge
an inappropriately low QPA.

- HHS should enhance its complaint process, including requiring IDR entities to report
insurers who miscalculate QPAs. Because of the QPA’s importance and the general effect
it can have on the healthcare system outside of the No Surprises regime, it is crucial that
regulators have the ability to promptly address insurers who incorrectly calculate QPAs.
SNMMI encourages the Departments to create a more specific and streamlined complaint
process. Currently, the complaint process outlined in 45 C.F.R. § 149.150 applies generally
to complaints against insurers who “may be failing to meet the requirements” of the
regulations. Moreover, it does not clearly indicate it should (or must) be used against
insurers who are inappropriately calculating the QPA. It merely indicates the Departments
“may . . . [r]efer the complainant to another appropriate Federal or State resolution process
[or] [r]efer the plan or issuer for an investigation for enforcement.”26

23 45 C.F.R. § 149.510(c)(4)(ii)(A).
24 For example, the regulatory text codifies an example of this standard describing a provider who appropriately
submits credible information “relating to the acuity of the patient that received the service, and the complexity of
furnishing the service to the patient, by providing details of the service at issue and the training required to furnish
the complex service.” In this example, according to the Departments, the provider’s submitted evidence “does not
clearly demonstrate that the qualifying payment amount fails to encompass the acuity and complexity of the
service,” and therefore, the certified IDR entity must select the offer closest to the QPA. Without information
regarding how the insurer calculated the QPA, e.g., how it accounted for acuity and complexity in the first instance,
it is unclear how any provider would have sufficient information to demonstrate that a QPA calculation failed to
appropriately take those factors into account.
26 See 45 C.F.R. § 149.150(b)(3).
SNMMI hopes the Departments will provide a more responsive and decisive complaint process to ensure repeat offenders and egregious errors do not influence the healthcare market. For example, the Departments could develop a federally operated, particularized complaint process for inappropriate QPA calculations.  

Lastly, IDR entities should be required to use the complaint submission process outlined in 45 C.F.R. § 149.150 and as modified above, not just encouraged to do so, when IDR entities conclude the QPA has been incorrectly calculated.

III. The Departments should Direct IDR Entities to Consider All Relevant Statutory Factors When Determining the Out-of-Network Rate

The Act plainly requires that IDR entities consider a number of relevant factors when determining the out-of-network rate. To ensure compliance with these statutory requirements, SNMMI urges the Departments to amend its regulations that give outsized consideration to the QPA by requiring IDR entities to “presume that the QPA is an appropriate payment amount.” This presumption is in direct opposition to the plain language of the Act and Congress’s intent in crafting the statutory language as it did, and as a result, we believe the Departments have exceeded their authority by establishing a presumption in favor of a single factor.

The Act stipulates that a certified IDR entity “shall” consider “the qualifying payment amount . . . and . . . information on any circumstance described in clause (ii) [the “additional considerations” factors], such as information requested [by the certified IDR entity], and any information [submitted by either party].” There is no indication that one factor should, or must, be weighed more heavily than any other, including singular prioritization of the QPA alone. Likewise, is the Act does not include any indication that non-QPA factors may only be considered to the extent they “clearly demonstrate” that the QPA is “materially different” from the applicable reimbursement amount. Moreover, the IDR entities’ considerations under the Act are self-executing -- the statute does not impute the Departments with the authority to dictate how certified IDR entities should reach payment determinations, nor does the statutory language require clarification. This is in contrast to other aspects of the surprise billing regime, such as the methodology for calculating the QPA, in which the Act specifically requires the Departments to issue regulations implementing the Act. Thus, in our view, the Departments’ approach is both counter to the clear statutory language and outside the Departments’ authority.

27 HHS has established primary enforcement of other provisions of the No Surprises Act. See 86 Fed. Reg. at 51,744 “HHS is of the view that states would not look to enforce these PHS Act provisions because . . . states would not have access to the submissions to assess compliance. . . . HHS therefore proposes to have direct enforcement authority for these issuer requirements in all states, unless the state notifies HHS of its intent to enforce.” The QPA is parallel to insurer reporting requirements as “states” (or stakeholders) would not have access to insurer submissions to monitor compliance.

28 86 Fed. Reg. 55995


30 See § 300gg–111 (c)(5)(C)(i)(I): “Considerations in determination [. . .] the qualifying payment amounts [. . .] Additional circumstances [. . .] The level of training, experience, and quality and outcomes measurements. . . .”

Our view is reinforced by an examination of the legislative history of the Act. The Departments’ approach reverts to a methodology explicitly rejected by Congress. Specifically, Congress considered and did not adopt a version of the Act which would have established the QPA as the de facto out-of-network amount. The final language represents a carefully crafted compromise among legislators in which the QPA is considered along with other pertinent, enumerated factors, without any single factor outweighing any other.

As a policy matter, overreliance on the QPA creates additional incentive for payers to exert inappropriate, downward pressure on the QPA, which is particularly problematic given the lack of transparency and oversight regarding this calculation, as discussed above. We are concerned that the current regulatory scheme leaves open the opportunity for gaming within the No Surprises regime and outsized contract negotiating power for insurers. Thus, not only is the presumption that the QPA is the appropriate out-of-network rate contrary to the intent of the IDR process as a neutral dispute resolution mechanism, it also may result in fewer in-network providers and reduced patient access to in-network care. For these reasons, SNMMI appeals to the Departments to follow the statutory model for dispute resolution outlined by Congress and amend its regulations to better reflect the plain language of the Act and Congress’ intent.

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SNMMI thanks the Departments for their consideration of these comments and the opportunity to engage with the Departments on these important issues. Wherever possible and appropriate, we encourage the Departments to issue subregulatory guidance as soon as possible to enable our members and other providers and insurers to develop the processes required to operate in compliance with this new regulatory regime. We would be pleased to discuss our recommendations with you at your convenience. In this regard, please contact Julia Bellinger, Director of Health Policy at jbellinger@snmmi.org or (703) 326-1182.

Sincerely,

Richard Wahl, MD
President, SNMMI