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Comment On: WCPO-2015-0003-0177
Claims for Compensation under the Energy Employees Occupational Illness Compensation Program Act

Document: WCPO-2015-0003-0214
Comment from J. Christopher Ballard, Critical Nurse Staffing, Inc.

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General Comment

Attached is Critical Nurse Staffing, Inc.'s comment letter, with attachments, regarding RIN 1240-AA08.

Attachments

Leiton.Ltr_02-17-2015

Critical Nurse Staffing, Inc.
— Caring for Energy Workers —

February 17, 2016

VIA UPLOAD AT REGULATIONS.GOV &
REGULAR U.S. MAIL

Ms. Rachel P. Leiton
Director
Division of Energy Employees Occupational Illness Compensation
Office of Workers' Compensation Programs
U.S. Department of Labor
Room C-3221
200 Constitution Avenue, NW, Suite S-3524
Washington, DC 20210

RE: ***RIN 1240-AA08*** - Comments on Proposed Rule Amending Regulations Governing Administration of the Energy Employees Occupational Illness Compensation Program Act

Dear Ms. Leiton:

This letter is sent on behalf of Critical Nurse Staffing, Inc. ("CNS" or "Company") to provide CNS' comments on the proposed rule amending the regulations governing the administration of the Energy Employees Occupational Illness Compensation Program Act ("EEOICPA" or "Act"), which were published in the Code of Federal Regulations on November 18, 2015. In that regard, the Company submits the following general comments first, followed by comments separated by section number within the proposed rule:

General Comments on the Proposed Rule

The proposed rule includes more than 100 changes with a large number having a direct impact on the provision of in-home healthcare services under the Act. Yet, despite that, this Company, an authorized provider under the EEOICPA since 2006, was never given the opportunity (*prior to the point in time the proposed rule was published in the Code of Federal Regulations on November 18, 2015*) by the Department of Labor ("Department" herein) to either review or provide input – from the perspective of an in-home healthcare company providing care under the EEOICPA – regarding the ramifications of the proposed rule[1]. To our knowledge, the only opportunity for any type of 'stakeholder' input prior to publication of the proposed rule occurred on January 15, 2015 and, that only involved certain members of the DEEOIC Interim Advisory Board. As we understand it, that 'listening session, during which no details of the proposed rule were discussed, as well as the suggestions of those who attended following it were

[1] In fact, we know of no authorized provider of in-home healthcare benefits under the EEOICPA who was provided the opportunity to review and consult with the Department regarding the rule prior to its publication.

never acted upon, making the 'listening session' itself unproductive.[2] The 'listening session' is the foremost example of the lack of transparency in this process.

First, that 'listening session' was just that – the individuals in attendance were not in a position to comment on what they were hearing. Second, it included only certain advocates and, more importantly, did not include other individuals and/or entities that the proposed rule will have an enormous effect on – one such entity being this Company. Third, as we understand it, that 'listening session' included a discussion of only broad topics and, the representatives of the Department who participated in it failed to mention the very specific changes to provisions within the rules that affect things from initial claim filing to how home health companies are to operate. Fourth, no participant in that 'listening session' was given a copy of the proposed rule prior to or during the session – how is it that the Department believed they could provide effective input on the proposed rule without being provided with a written copy of same?

In our opinion, the failure of the Department to solicit input from all 'stakeholders' in the proposed rule prior to publication was also a mistake for at least two reasons. First, we believe it would have been appropriate for the Department to give all 'stakeholders' the opportunity for input before promulgating new rules in a program such as the EEOICPA. Second, we believe this was a mistake because most, if not all of our concerns with the proposed rule could have been addressed prior to publication if we had been given the opportunity to review and consult with Department representatives.

We would also point out that one of the stated strategic goals of the Office of Workers Compensation Programs ("OWCP"), the entity charged with responsibility over the administration of the EEOICPA within the Department, is to promote collaboration and outreach with 'stakeholders' and customer groups. The OWCP is on record as stating that it believes that '. . . communication, collaboration and outreach with claimant communities and stakeholders is essential to the successful accomplishment of its mission.'[3] With respect to allowing 'stakeholders' the opportunity for input, many of the comments contained herein, as well as those made by others during this process, would not be necessary had the Department simply asked for input prior to publication in the Code of Federal Regulations ("CFR").

Related to this is the fact that the Company also believes it is essential that the Advisory Board on Toxic Substances and Worker Health ("Board") be seated and have the opportunity to provide its own comments on the proposed rule prior to implementation. As you are well aware, that Board will be comprised of members of the interested community who would be able to

[2] This statement is based on the content of the February 1, 2016 letter submitted to the Department from the DEEOIC Interim Advisory Board.
[3] These goals and statements are taken directly from the Office of Workers' Compensation Programs 2014-2018 Strategic Plan, published in October 2014.

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provide valuable insight into the practical effect of the proposed rule on the administration of the Act as it is to be comprised of advocates, scientists and other interested parties with years of experience dealing with the Act. By not waiting until after that Board had been seated and had the opportunity to consider the effects of the proposed rule, we believe the Department is missing out on their learned knowledge, experience and insight.

§30.5 – Definitions

We believe that all prior bulletins issued by the Department related to the administration of the EEOICPA should be part of the proposed rule; this is especially true for the content of any prior Department bulletin which is currently in 'full force and effect'. Further, subsection (ee) of this section defines what is meant by the phrase 'qualified physician'; however the Company believes that the definition is not broad enough and, would like to see both physician's assistant as well as nurse practitioner (*as defined by the state in which the individual is licensed*) be added to the definition. In the Company's opinion, this is necessary and appropriate because there are individuals who qualify for services under the Act who live in areas not served by physicians on a regular basis.

We also believe that the following words/phrases, all of which can be found throughout the proposed rule, need to be defined within the proposed rule:

- Accepted Industry Standard;
- Automatic Exclusion;
- Credible;
- Explicit Diagnosis;
- Extensive Delays;
- Fully Develop Claim;
- Fully Rationalized Medical Report;
- Misleading, Deceptive and Unfair; (As used in §715(i))
- Non-Automatic Exclusion;
- Other Evidence;
- Probative Value;
- Probative Factual Evidence;
- Probative Medical Evidence;
- Trustworthy Records;
- Usual Medical Necessity Requirements.

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§ 30.100 – Claim Filing

The proposed rule requires that the employee signed the Form EE-1 and, states that submission of the form will necessary for the OWCP to 'fully develop' any claim for benefits. The Company is concerned about this language and, believes it needs revision. What happens in an instance where an employee will not be able to sign Form EE-1, such as when their physical condition makes signing impossible? What procedure is the claimant and/or his family and authorized representative to follow in that instance – as written, the proposed rule provides no guidance for this example.

§ 30.113 – Requirements for Written Medical Documentation

The proposed rule states that, in the event the employee submits a certified statement by a person with knowledge of the facts, medical records which are relevant to the employee's claim for benefits no longer exist, the OWCP may consider other evidence to establish a diagnosis and date of diagnosis. However, the proposed rule does NOT define what is meant by the phrase 'other evidence' in this context. Without including a definition, this phrase will be subject to widely differing interpretations depending upon who is reviewing the claim for benefits. It is important that uniformity exist in examining submitted claims and, as a result, the Company urges the Department to specifically define what the phrase 'other evidence' means in this context and when used throughout the proposed rule.

§ 30.320 – Reopening Claims after FAB Decision

This section states that, at any time after the FAB has issued a final decision, an employee may file a written request to have the claim reopened. The section goes on to state the claimant must submit 'new evidence' of a diagnosed medical condition in order to have the claim reopened by the Director. However, in our experience, we have seen instances where a claims examiner failed to take into account all relevant evidence in reaching their initial determination and, we believe the decision to reopen any claim should also include those instances where the supporting evidence is not properly taken into account.

§ 30.400(c) - What are the basic rules for obtaining medical treatment

This section includes language which appears to put the Department in the position of trying to enforce the laws of a specific state or states when it talks about possession of ". . . all applicable licenses required under State law". The state at issue is the only entity that can enforce the licensing laws. Further, the Company believes that only a state-issued, final determination regarding licensure issues in that state is an appropriate standard to be used by the Department for determining whether a hospital or provider of medical services is eligible to

provide care to the employee. Relatedly, the Company also takes the position that the findings of any state should only apply to that state – not 'across the board'.

This section also contains the following new language, "OWCP may contract with a specific provider or providers to supply non-physician medical services or supplies." The language of the proposed rule conflicts with the Act's language in that the Act discusses individual choice in choosing a medical provider.[4] Further, the meaning of this sentence is unclear to the Company – does this mean that the Department retains the right to contract with a specific provider to supply non-physician medical services or supplies at any time and under any circumstance? If so, could the Department please explain where the grant of such authority to it comes from?

Based on the 'plain' meaning of the language at issue, the Department is taking the position that it has the right to contract with a specific provider to supply non-physician medical services or supplies only under certain circumstances – can the Department outline under what circumstances it will exercise this right? Further, and as written above, can the Department explain where it believes the grant of such authority comes from?

§ 30.403(c) – Paying for Home Health Care, Nursing Home, and Assisted Living

The Company opposes the proposed changes in section §30.403, especially the addition of subparagraph (c). Subparagraph (c) includes the proposed addition of two new forms to the initial authorization process – EE-17A and EE-17B. The Company believes the requirements of these forms and the procedure related to them will have the effect of forcing authorized in-home healthcare providers to disregard established home health industry standards, as well as Federal and State law and regulations with regard to the timely initiation of services.

Specifically, the Company believes that the introduction of Form EE-17A, which is to be completed by the employee, is problematic. As the Department is already aware, many employees are elderly and suffer from significant medical issues. The introduction of an additional form creates another barrier for them in seeking the medical benefits that they are entitled to. Additionally, the proposed rule does not explain how the process will work in the following situations:

- When an employee has a 'gap' in their authorization for benefits;
- When an employee is restarting benefits under the EEOICPA; and/or
- When an employee wants to change their treating physician.

[4] See §7384(b) of the Act.

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In these situations, will the employee and physician be forced to complete new EE-17A and EE-17B forms? Will the employee be the only one forced to complete a new form? Related to these issues is another question, that is: If the employee makes a mistake in completing the form, what will be the process for correcting the form?

Relatedly, Bulletin 07-20(16) '*Emergency Situations*' discusses, as the name implies, emergency situations warranting short-term, preliminary authorization for in-home healthcare services – How will emergency, short-term authorizations be handled under the proposed rule? What is the process for handling them under the proposed rule going to be? None of these scenarios are addressed in the proposed rule.

With respect to form EE-17B, the proposed rule contains no time frame for getting the form from the Department to the physician – how will this be handled? How will the form be supplied to the physician – regular mail, overnight delivery, facsimile, email?[5] What will be the process for ensuring that the form was received by the designated physician? Will the Department be taking responsibility to ensure that the EE-17B is returned to it in a timely manner? If not, who does the Department believe will be responsible for making sure the form is returned – the physician? The employee? What is the time frame in which the Department expects these forms to be returned to it? If they are not returned within that time frame, will the Department take any steps to determine what has occurred? If not, does the Department expect someone else to take the responsibility and, if so, who?

Form EE-17B also states that the physician will ". . . attach a Letter of Medical Necessity that contains both a plan of care and the rationale for my conclusion that the prescribed home health care, nursing home or assisted living services are medically necessary for treatment of the DEEOIC accepted condition(s) listed above." Can the Department provide a sample of the type of letter it expects? As written, the Company believes the proposed language is too vague and, places too high a burden on the employee and physician; similar vague language has caused legitimate claims to be denied because employees and their physicians do not know what the Department expects of them.

Also, as the Department should be aware, a 'Plan of Care' is typically generated from an RN comprehensive assessment. How is the Department going to notify the home health agency of an upcoming comprehensive assessment that needs to be scheduled in a timely manner so to provide the treating physician with the required information prior to the face-to-face renewal

[5] Based on the Form EE-17A and EE-17B we have found on the Department's website, it appears the Department will require that these forms be mailed to its London, Kentucky post office box, which will likely have the effect of prolonging the process even more. *See* January 2015 version of Form EE-17 and EE-18, both of which are included herewith and incorporated by this reference.

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appointment? Further, the Department does not define what it expects when it refers to a 'timely face-to-face physical examination' of the employee – can the Department articulate a meaning for this language so that home health agencies as well as physicians understand what is expected of them?

Put simply, without a clear process mapped out with regard to implementing the additional steps the proposed rule contemplates, the Company believes the time needed to complete the new process will be longer than allowed by other applicable laws and regulations. In support of this, the Company points the Department to the following Federal and State of Colorado regulations:

42 CFR §484.55 – Condition of Participation: Comprehensive Assessments of Patients Standard: Initial Patient Visit states:

> *(a)(1) A registered nurse must conduct an initial assessment visit to determine the immediate care and support needs of the patient; and for Medicare patients, to determine eligibility for the Medicare home health benefit, including homebound status.* ***The initial assessment visit must be held either within 48 hours of referral, or within 48 hours of the patient's return home, or on the physician-ordered start of care date.*** *(**Emphasis Added.**)*

Code of Colorado Regulations 1011-1 – Chapter 26, Section 7.9, Initial and Comprehensive Assessments (A) (1) states:

> *(A)(1) A registered nurse shall conduct an in initial assessment visit to determine the immediate care and support needs of the consumer.* ***The initial assessment visit shall be held either within 48 hours of the referral, or within 48 hours of the consumer's return home, or on the ordered start of care date.*** *(**Emphasis Added.**)*

These are regulations this Company, as well as others, must comply with on a daily basis and need to be considered by the Department before implementation of the additional processes outlined in this section of the proposed rule are finalized.

The language contained in proposed rule §30.400(c) relates to this issue as well. It states that a provider of medical services or supplies may furnish appropriate services, drugs, supplies and appliances, ***so long as such provider possesses all applicable licenses required under State law*** and has not been excluded from participation in this program under subpart H. (***Emphasis Added***). The Company supports the inclusion of such language by the Department in the proposed rule; however, by including the new processes outlined in this section of the proposed

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rule, the Department is jeopardizing the state issued license of any authorized home health provider because it is impossible to complete all of the steps now involved in the initial authorization process within the 48-hour standard.

Also related to the issues identified above are other issues, such as: How will the employee be able to obtain the form itself? How will the employee know that they need to complete and/or file the EE-17A form? Given the fact that, within the current system of initial and/or renewal authorization, the four district offices are 4-8 weeks behind, has the Department budgeted for the hiring and training of additional staff to accommodate the heavier workload that will be created by the new forms? How does the Department intend to handle situations in which the employee misidentifies the physician who made the diagnosis? Must the employee begin the process over from square one? What will be the process to change the information on Form EE-17A? Will the form cover every physician within a particular practice group? As the Department should be aware, it is not uncommon for different physicians within a practice group to provide treatment to patients of other physicians within their group – will the proposed rules allow for this and, if so, what is the process? If not, how is the Department going to handle such a situation?

Also, and as this Company believes the Department is already well aware, many employees have been diagnosed with complex medical issues that require the intervention of a Medical Specialist. In these situations, due to their expertise, it is often the Medical Specialist ordering home care. CNS believes that misidentification of the treating physician could create significant delays in receiving timely home care if there is no clear, time sensitive process in place to address this concern. Another question involves the emergent start of care process – it is not discussed at all within the proposed rule, in such situations, the need for EE-17A would cause significant delay in providing timely home care for those clients being discharged from an acute care facility due to their covered diagnosis.

Further areas of concern not addressed in this section include the vagueness of the continuation of the newly introduced process beyond the initial authorization. One sentence of the proposed rule states that ". . . this particular pre-authorization process must be followed only for the initial claim for home health care. . .". However, another sentence states "[A]ny subsequent request for pre-authorization must satisfy OWCP's usual medical necessity requirements." How are these two sections to be interpreted? Does the language of the second mean that Form EE-17B will be needed for subsequent continuation of care after the initial 180-day approval? Simply put, what will be the procedure for continuation of home care after the initial 180 day approval period expires? And, will either the EE-17A or the EE-17B need to be submitted to the Department after the initial 180 day period ends? Will physicians need to complete a new Form EE-17B at each renewal?

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Relatedly, Bulletin 07-20(2) states that in-home healthcare requests will routinely be submitted to the Department's bill pay agent via facsimile, mail, or electronically and, that requests may be received by district staff by way of a written request from the employee, authorized representative or another service provider. That same bulletin goes on to say that any service request does not need to come directly from the employee to be considered valid – will the Department allow the in-home healthcare provider to submit either EE-17A or EE-17B on behalf of the employee or physician?

Finally, another concern of the Company is the fact that many physicians and physician provider groups, which we work with, have expressed frustration regarding the amount of paperwork they need to complete to help their patient(s) obtain medical benefits under the EEOICPA. We believe this is a legitimate concern on their part. Further, we also believe that the inclusion of these additional forms will continue to add to this frustration and continue to alienate potential providers. The lack of providers in some remote areas (*Navajo Reservation in Arizona for example*) has already severely undermined the ability of eligible beneficiaries to receive the medical benefits awarded to them under the EEOICPA.

The Department should consider all of these issue prior to implementing the significant, proposed changes to §30.403(c).

§30.405(b) & (c) – Changing Treating Physicians

The proposed rule outlines new language for subparagraphs (b) and (c) of this section. However, some of the new terms and/or phrases, such as, 'probative factual and/or medical evidence', 'probative evidence' and, 'as appropriate', all of which appear in subparagraph (b), are not defined by the Department. This failure by the Department makes it impossible for an employee to know exactly what the Department will need in order to allow them to change physicians – something that can be corrected by defining these terms/phrases. Additionally, the Company believes that all interested parties can agree that there are situations where it is necessary for an employee to change physicians for reasons not discussed in the proposed rule – how will such situations be addressed by the Department?

With respect to subparagraph (c), the addition of the language allowing the Department to deny a request for a physician change if it determines that ". . . the reasons submitted are not both credible and supported by probative evidence. . ." is too vague and subjective and, the Department needs to specifically outline the bases for denying a requested change. Without doing so and, as written, subparagraph (c) will lead to widely varying responses to requests to change physicians.

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Additionally, nowhere within this section does the Department explain how this new process will work; how far in advance of a renewal should an employee make such a request, or what the time frame will be for the Department to respond to a request by an employee? Again, the Company believes it is in everyone's best interest to be as specific as possible with respect to these issues so as to eliminate any confusion or misunderstanding by the employee regarding how this process will work going forward.

§30.410 – Can the Department Require an Employee to be examined by Another Physician

The Company is concerned that the newly added subparagraph (c) does not address important issues related to obtaining a second opinion. One such issue is how the Department would address a situation in which the employee is not physically able to attend the second opinion appointment scheduled by the Department. An employee who suffers from conditions which make them too ill to travel long distances is simply not the same as a refusal to attend an appointment. As a result, we believe such an explanation from the Department regarding how this proposed rule would be implemented is necessary in order to fully understand the proposed rule.

As an example, many employees live in remote areas with few Department authorized providers readily available. A fact which is compounded because many of these same employees are not physically capable of making long trips to Department designated second opinion appointments. In a situation such as this, would the Department take the position that the employee's inability to travel to the second opinion appointment equates to a 'refusal' to attend, thereby resulting in the Department either administratively closing the claim or suspending adjudication of the claim?

Giving the Department the power to close or administratively suspend a claim because the employee is too sick to travel or because the designated second opinion physician is too far away for the employee to safely travel to is putative and, we believe has no place in a remedial statute such as the EEOICPA. Situations in which the Department would be allowed to take such drastic measures against an employee need to be extremely limited and more specifically outlined in the proposed rule.

Also, related to the issue of obtaining a second medical opinion is that fact that most of the second opinion physicians to whom employees are sent are also Contracted Medical Consultants ("CMC") of the Department. The Company believes this violates two of the Department's conflict of interest rules as enumerated in Bulletin 14-04. Further, it has long been the Department's stated position that the 'treating provider carries the most probative value'; however, in our experience at least, the Department has a 'track record' of honoring the orders of

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CMC over the opinion of the employee's 'treating provider', many of whom are also specialists in their field.

The EEOICPA was implemented to cure bureaucratic hurdles and, we are afraid that the implementation of the language of subparagraph (c) would undermine that goal. In our opinion, subparagraph (c) is an effort by the Department to save costs rather than provide the employee with the services, appliances and, supplies prescribed or recommended by a qualified medical professional, as the EEOICPA requires in §7384(t). In this regard, the Company would point out that it has never experienced a situation where the Department has ordered an employee to attend a second opinion appointment where the treating provider's prescribed home care hours are low.

§30.411 – Differing Medical Opinions

The proposed new language which adds subparagraph (d) to §411 is identical to the language in newly added subparagraph (c) of §410, except the language in §411 applies to 'referee' examinations. As a result, the Company believes that its comments included in response to §410 are equally applicable here and, incorporates the same by this reference.

§30.601 – Who May Serve as a Representative?

The Company requests the Department specifically identify what document it is referring to when it writes in this proposed rule ". . .the standards regarding conflicts of interest adopted by OWCP." The Company believes the Department is referring to its Bulletin 14.04, issued on July 1, 2014; however, it requests clarification on this issue. Further, the Company believes this proposed rule creates a double standard between employees and their family members and those contracted medical providers performing second opinions and referee examinations on the Department's behalf.

As the Department is well aware, under the existing policy, it is a conflict of interest for an authorized representative to be employed in any capacity by the in-home healthcare provider who is providing care to the employee under the EEOICPA. Yet, according to Department policy, it is not a conflict for a second opinion or referee physician to also be a CMC for the Department. This represents an obvious double standard and, needs to be addressed by the Department.

The fact of the matter is that many times the employee has only one family member, charged with the responsibility of taking care of all of their daily needs, both financially and physically. This makes that family member the most qualified individual to act as both the authorized representative as well as the personal care aide for the employee. In many cases, as currently written, this rule forces employee's to designate distant friends or relatives as their

authorized representative because their immediate family member(s) act as their primary care giver(s), involved in providing day-to-day care. Thus, these relatives become employed as home health aide(s) or equivalent by the in-home healthcare provider and, under §30.600, these relatives are not allowed to be the authorized representative. Because of this Department policy, the employee is placed at a great disadvantage. Simply put, they have to trust someone who is not involved in their day-to-day care to be an advocate for their needs. The Company believes these types of situations need to be addressed in the revised rule.

§30.700(b) – Seeking Prior Authorization

The section addresses the issue of prior authorization for a medical procedure; however, it does not address the procedure for obtaining authorization. This will create a problem for employees 'threatened' with non-payment by the Department for medical procedures which are obviously related to their covered condition simply because the newly created requirement of pre-authorization was not completed. The Department needs to outline a procedure related to this proposed new rule. Further, the Company believes the procedure needs to be uniform across all Department offices and, that is should be explained in the proposed rule.

§30.701 – How are Medical Bills to be Submitted?

The Company is opposed to that portion of the proposed rule pertaining to the 'potential' adoption of the Home Health Prospective Payment System ("HHPPS") as outlined in subparagraph §30.701(c)(ii). We believe that this section of the proposed rule is vague and lacking sufficiently detailed information to evaluate the merits of the proposed change to billing. Without a more detailed explanation, the Company, as well as other 'stakeholders', is left to speculate on how such a significant and complex change will impact them – this is particularly true for employees and medical providers under the EEOICPA.

As the Department is fully aware, the intent of the EEOICPA, as stated in section 7384(t) of the Act, was that the Federal Government **shall** furnish the services, appliances, and supplies prescribed or recommended by a qualified physician for the covered illness. If the HHPPS system is adopted, we believe that will result in the reduction of benefits available to employees because of its differing eligibility and treatment model. The EEOICPA was formed to provide monetary compensation and ongoing medical benefits, including long term and in-home care for eligible employees stricken with chronic-lifelong diseases, caused by their occupational exposures. These chronic diseases led to the need for constant medical supervision and in-home care.

Contrast that with Medicare, the system for which the HHPPS system was developed. Medicare is a federal insurance program providing services that primarily focus on short term,

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acute care for the elderly and disabled, with the goal of treatment being for the patient to return to his/her previous level of health and physical state. Medicare comes with an entirely different set of regulations, processes and billing procedures. The fact that these programs have two very different philosophies will make delivery of care for EEOICPA beneficiaries, while trying to incorporate the philosophies and practices adopted by the Centers for Medicare and Medicaid Services for Medicare, extremely challenging and, we believe, will lead to a reduction in the quality of care employees receive in the long run.

Additionally, the vagueness of the phrase 'may adopt', as contained in this section leaves all interested parties (*employee, employee's physician, in-home healthcare provider*) with more questions than answers. The Company believes the inclusion of this language into the proposed rules could simply be a placeholder, allowing the Department to merge the EEOICPA program directly into CMS, thus impacting every portion of the employee's care and benefits. The Company believes this to be true, regardless of the employee's payer source. If this change in billing systems is adopted by the Department, it would unquestionably cause authorized in-home care providers to change their entire structure to be compliant with CMS guidelines. Further, we also believe such a change could result in a reduction of the quality of care provided to the employee. By implementing the proposed rule outlined in subsection (2)(c), we believe in-home healthcare providers would be required to obtain accreditation with CMS, a cumbersome, complex process that takes time. Our question is – how would the Department handle this potential complicating factor in delivering care to the employees who have qualified for it under the EEOICPA while that process is ongoing? How would costs related to care be divided between the EEOICPA and Medicaid/Medicare programs?

Lastly, the Company requests further thought, consideration and discussion occur prior to implementation, if the Department ever decides that implementation of the HHPPS system is necessary, of the proposed rule as outlined in subsection (2)(c), as it will impact and change the entire structure of the delivery of in-home healthcare services under section 7384(t) of the EEOICPA. To our knowledge, having checked with other EEOICPA authorized in-home healthcare providers, there has been no dialogue between the Department and any EEOICPA authorized in-home healthcare provider regarding this proposed rule. The Company believes that such 'stakeholder' engagement is vital prior to implementation of such a major shift in the process of delivery of in-home healthcare services to employees to ensure high quality and continuity of care as mandated by the Act.

§30.715(i) – Grounds for Excluding a Provider from Payment

The Company believes that the proposed rule needs to outline the process for notifying the Department of a change in provider status as discussed in this subsection.

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§30.715(j) – Grounds for Excluding a Provider from Payment

The Company believes that the proposed rule needs to specifically enumerate what is meant by that portion of the proposed rule which states ". . . that OWCP finds to be misleading, deceptive or unfair." The Company further believes that without doing so, it is impossible to understand either the intended or actual meaning of this new subsection of the proposed rule.

§30.717(a) – When are exclusion Procedures Initiated?

While the Company believes the revised language of this section is certainly a good thing, we believe it to be problematic as well as a result of the lack of detail. First, it fails to outline a process for reporting alleged wrongful activities. To whom within the Department would an interested party send information related to the engagement of prohibited activities by a physician, hospital or provider of medical services? Who, within the Department, will be responsible for forwarding such allegations to the Department's Office of Inspector General's ("OIG") office? The revised rule does not identify such an individual or individuals; nor does it identify the process by which such information should be submitted either.

Second, does the revised rule prohibit an interested party from reporting alleged wrongful acts directly to the Office of Inspector General? If so, why? Third, under the language of the proposed rule, it is unclear to the Company whether it is automatic that all allegations received by the Department will be forwarded to the Department's OIG's office or, whether there is discretion on the part of the Department's representative regarding whether or not to forward it? If discretion is allowed, on what factual bases will the Department's representative be making the determination as to whether to forward such information to the Department's OIG's office? Fourth, subparagraph (i) appears to allow the Department to exclude a provider as a result of its failure to report 'administrative' changes within the organization to the Department. In our opinion, punishing a provider for such an oversight is 'putative' and akin to using a sledgehammer to kill a moth – we believe this section needs to be rethought.

The Company believes all of these issues/questions need to be addressed and or answered in the revised rule before it should be formally adopted.

§30.718 – Notification of Excluded Provider

The Company has questions regarding what happens to the patients of an excluded provider, particularly an in-home healthcare provider. Will the Department be involved in transition/discharge procedure for patients of the excluded provider? Can the Department outline how the transition/discharge process will work in a situation in which the provider has been excluded? Will the fact that their chosen in-home healthcare provider has been excluded from

participation in the EEOICPA have any effect on the benefits of the patients of that excluded provider? Will the 'displaced' patients need to seek an immediate reauthorization or is their approval for in-home care immediately transferrable to another provider? What will be the process by which they will be allowed to choose a new in-home healthcare provider? Will the Department be assisting them with that process in any way? If so, how?

Will the Department alert other in-home healthcare providers of the fact that the excluded provider has, in fact, been excluded from participation in the EEOICPA? This may be necessary to allow those other providers the opportunity to prepare for assuming the care of the 'displaced' employees. If so, how does the Department anticipate that process working?

§30.719 – Requirements of Provider's Response and Department's Decision

Subsection (c) states that the provider may inspect or request copies of information in the record 'at any time' prior to the issuance of a decision; however, that same subsection also states that the provider must make such a request within 20 days of the receipt of the letter of intent from the Department. These statements contradict one another – if the provider may inspect or request copies of information in the record 'at any time', then the language regarding making such a request within 20 days of the receipt of the letter of intent must be removed from this subsection.

Additionally, the procedure for exclusion fails to explain how the Department intends to prevent the owner of an organization which has been excluded from simply forming a new organization, reapplying to be an authorized provider and, then beginning to provide care under the EEOICPA to employees. Has this been considered by the Department? If so, what is the Department going to do to make sure that a disqualified individual does not simply either form another organization or become involved with another, then existing provider under the EEOICPA?

§30.725 – Effects of Non-Automatic Exclusion

Can the Department define exactly what the meaning of the phrase 'non-automatic exclusion' as contained in this section? Can the Department explain what it considers to be the difference between an 'automatic exclusion' and a 'non-automatic exclusion'?

§30.901 – Determining the Extent of the Employee's Impairment

Why did the Department take out any reference to the American Medical Association's Guidelines ("AMA Guidelines")? The AMA Guidelines represent the standard in the industry for determining impairment and, are routinely utilized by physicians across the United States to

make determinations regarding the percentage of impairment. The Company believes deleting any referenced to them as the standard is a mistake. This is because, by doing so, the Department will allow physicians to use their own standard for determining not only if impairment exists, but the extent of same. In other words, by not referencing the AMA Guidelines as the standard, the Department is reducing the chance that physicians who do these ratings will be evaluating impairment using the same standard and/or methodology. The Company believes any impairment rating should be based on the current AMA Guidelines and, that a reference to those needs to be reinserted into this section.

§908(b) – Evaluating New Medical Evidence Challenging the Impairment Rating

Again, the Company believes any evaluation of impairment must be based on the latest AMA Guidelines for Impairment and, would urge the Department to insert language into this section which makes those guidelines the standard.

CONCLUSION

The Company believes that the issues brought up in this comment letter, along with other issues brought to the attention of the Department by other individuals and organizations involved in the day-to-day implementation of the Act must be addressed by the Department prior to implementation of the proposed rule. The Company urges the Department to do just that at this time.

Sincerely yours,
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