CQRC COUNCIL FOR QUALITY RESPIRATORY CARE

March 23, 2017

Tom Price, M.D.
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Secretary Price and Administrator Verma,

I am writing on behalf of the Council for Quality Respiratory Care (CQRC) to provide you with our suggestions as to how the new Administration could strike the right balance and reduce the immense regulatory burden placed on home respiratory therapy suppliers, while still remaining vigilant to protect against actual fraud and abuse. As noted in detail below, Medicare contractors acknowledges that nearly 100 percent of beneficiaries who are prescribed home respiratory therapy actually meet the medical necessity requirements, so it is not clear why claims should be denied. In this letter, we provide background on the problem and offer specific solutions.

The CQRC is a coalition of the nation's seven leading home oxygen and sleep therapy providers and manufacturing companies. Together we provide in-home patient services and respiratory equipment to more than 600,000 of the more than one million Medicare beneficiaries who rely upon home oxygen therapy to maintain their independence and enhance their quality of life. Similarly, we provide homecare services, equipment and supplies to more than one million Medicare beneficiaries with Obstructive Sleep Apnea (OSA).

In sum, we request that CMS reduce the overly burdensome requirements placed on home respiratory therapy suppliers by:

- Using its discretionary authority to remove home respiratory therapy equipment from the Face-to-Face examination (returning to the physician visit requirements in the original Local Coverage Determination (LCD)) and written order prior to delivery requirements (returning to previous requirements related to verbal and written orders), which is from where the burdensome documentation requirements stem;
    - If this change cannot be implemented quickly, we recommend that CMS under its discretionary authority rely upon the Certificate of Medical Necessity (CMN) to establish that a face-to-face visit occurred, rather than requiring patients' medical records, and to allow the CMN (for home oxygen therapy) and the required prescriptions and sleep test results (for home sleep therapy) to constitute a valid written order for purposes of dispensing home

respiratory therapy equipment so long as these documents includes the detailed written order elements and the date of the physician visit (which could be added to the current CMN as date last seen);

- Modify the proof of delivery requirement to allow for alternative documentation options;

- Stop contractors from auditing the same patients using different dates of service; and

- Streamline the audit process to avoid duplicative audits of the same patient with a different date of service.

If CMS believes there will be a delay in eliminating the face-to-face examination and written order prior to delivery requirements, we encourage CMS to build on the work being done to establish electronic submission of order information and create a clear set of structured data that prescriber must submit and to which physicians can attest.

I. Background: Home Respiratory Therapy Suppliers Have Been Subject To Overly Burdensome Regulations for Too Long.

The CQRC strongly supports eliminating fraud and abuse in the Medicare program. These efforts should be rational, balanced, and targeted to ensure that scarce Medicare funds are directed at activities that appropriately need to be curtailed. Unfortunately, the current system is broken. It is overly burdensome and focuses on technical documentation issues, rather than rooting out actual fraud and abuse in the system. Despite the ongoing cooperation and support that CQRC members provide in fighting fraud and abuse, the volume of auditing requests has increased ten-fold. In many of these cases, the resulting denials received do not relate to actual fraudulent activity, but rather involve auditors retroactively applying new rules, ignoring documents submitted, and misinterpreting or overzealously searching for technical errors in Medicare requirements. While the initial denial rate is substantial, the objective Administrative Law Judges (ALJs) and the new contractor reviewing appeals (C2C) overturn the vast majority of these denials in favor of the suppliers. These judges often find that auditors have ignored documents submitted by suppliers and/or misinterpreted the regulatory requirements.

The current overly burdensome audit process places Medicare beneficiaries at high risk. For example, if a supplier is not paid for services and equipment for what could be three or more years, it is unlikely the supplier will assume the resulting risk of not ever being paid. Suppliers are not in the position to continue

serving the beneficiaries, unless the beneficiaries agree to pay out of pocket. When a supplier takes such a risk and wins on appeal, beneficiaries are asked to pay multiple years of co-payments at one time. Given the egregious nature of some of the audit results, we anticipate that more than three-quarters of the denials will be overturned through the lengthy review process. In a recent meeting, the contractor C2C indicated that it finds in favor of the supplier for more than 80 percent of claims for home oxygen therapy that were initially denied. It is unfair to beneficiaries not to require audit contractors to get it right during the initial review. The current auditing practices if left unchecked will result in a *de facto* elimination of the Medicare home respiratory benefit.

Over the years, CQRC members have collected and reported examples of the egregious and burdensome process. These examples include:

- ***Contractors, when reviewing the medical record, do not recognize that Chronic Obstructive Pulmonary Disease (COPD) is chronic and not curable.*** When a physician clearly documents that the patient has COPD in the record, the contractors do not view COPD as constituting a continuing need for the only treatment available for the disease and deny claims. The CQRC has sought to allow physicians to clarify, consistent with medical text books, that the physician views the diagnosis of COPD as also indicating that the patient had a chronic condition and a continued medical need for home oxygen therapy. The medical community recognizes that once a patient has been diagnosed with COPD, he/she will continue to require home oxygen treatment.

  "[R]elatively little can be done to reverse the disease process…and treatment is limited chiefly to prevention and control of infection, relief of bronchoconstruction, and general rehabilitative measures. Rehabilitative programs can definitely improve a patient's quality of life in spite of the fact that the pathological changes that may not be reversed"

  West, John B. Pulmonary Pathophysiology: The Essentials 8th ed. 64 (2013).

  Physicians take as a given that once a patient has COPD, the disease is chronic and the patient will not recover from it. If a physician is using "COPD" as shorthand for this medically accepted concept, he/she should have the opportunity to submit an attestation or otherwise amend the record to clarify the point, regardless of the timing of the amendment/attestation. Currently, such clarifications are not only prohibited, but contractors have threatened legal action against anyone seeking to provide such a clarification.

- ***Contractors fail to read the record and deny claims even though the supplier submits the required documents***. For example, a denial may be noted as due to an illegible physician signature even though the physician signs and types or prints his/her name or the record is clearly part of an authentic hospital record, with entries from multiple parties, only some of which have not provided signature attestations. Another example relates to denials which result from the contractor concluding the written prescription is not valid because the physician's prescription pad includes the date on the top of the document rather than next to his/her signature.

- ***Contractors do not request a specific document but deny the claim because that document was not provided.*** In some cases when an auditor supplements its request for records and the supplier complies, the contractor fails to correlate the new information with the previous file and denies the claims. For example, claims have been denied because the contractor says the need of the patient was 12 months and that time has tolled. However, the medical documentation submitted clearly states a lifetime need. Although the contractor has authority to reopen the claim and resolve the matter quickly, it routinely subjects the supplier to another level of appeal, additional payment delay, and unnecessary administrative costs.

- ***Contractors audit the same patient for multiple service dates.*** Even if the supplier provides a single set of documents that are accepted for one of the service dates as sufficient, the auditor deems that the documents are not adequate to support medical need for the other dates of service for the same patient and denies the claims for these other service dates.

- ***Contractors misinterpret Medicare requirements***. For example, some contractors refuse to allow suppliers to be paid for supplies shipped based upon a corrected physician's prescription when the CMS manual clearly recognizes that such corrections or clarifications to physician orders will be effective as of the original or initial data of service.

- ***Denials of claims submitted by a supplier who has taken over patients from another supplier that went out of business or because the prior supplier did not adequately respond to an audit for the patient.*** There is no alternative documentation that contractors will recognize to address the problem facing transitioning patients.

- ***Contractors refuse to accept new or corrected proof of delivery documents, even when it is impossible to provide an original document.*** Contractors are denying claims if the original proof of delivery document is not provided when requested or if the signature date on the proof of delivery document does not match the date of service audited exactly. This stance

creates a serious problem when a supplier has agreed to accept a patient who was receiving home respiratory therapy prior to enrolling in Medicare and already has the equipment in their home. Similarly, contractors provide no alternative for the original document even if the original has been lost, misplaced, or was misfiled.

II. Common Sense Solutions: CMS Should Focus Efforts on Eliminating Fraudulent Suppliers and Be Less Concerned about Technical Documentation Requirements.

The current documentation requirements and audit process are highly inefficient, costly, inconsistent, and burdensome for both suppliers and the federal government. They also create problems for prescribers and patients. Thus, the CQRC is pleased that CMS is reviewing the underlying policies that have created the overly burdensome documentation requirements, which have led to the broken audit process. We ask that CMS reduce the unnecessary, often-duplicative documentation requirements that have become even more burdensome because of the draconian implementation of the by Medicare contractors.

Specifically, the CQRC asks that CMS recognize that home respiratory therapy organizations are designated as "suppliers" under the Social Security Act (SSA). They do not have authority to diagnose patient conditions or prescribe medications or therapies. It is the sole prerogative of the prescribing health care professional recognized by CMS to diagnose each patient's condition(s) and prescribe the medication or therapy that the prescriber believes in his/her medical judgment is medically necessary for the patient. It is the job of the supplier to fill that prescription and make sure that the patient receives refills as directed by the prescriber. Thus, the home respiratory therapy supplier is more akin to a pharmacist who is required only to provide the prescription (and when required a prior authorization) when dispensing medications. We ask that CMS consider our recommendations and the substantial regulatory burden that the current documentation requirements place on home respiratory therapy suppliers in light of these basic facts.

Second, we also ask that CMS recognize that the prescribing of home respiratory therapy is primarily an objective, rather than a subjective, process. This fact differentiates it from other types of durable medical equipment (DME). Therefore, while some additional documentation may be appropriate for power mobility devices, as the Congress has indicated, it does not mean that such requirements are appropriate for home respiratory therapy equipment and supplies. There is no "one-size-fits-all" approach.

A. The CQRC Recommends that CMS Eliminate Overly Burdensome Regulations that Duplicate Other Requirements.

Therefore, as described in detail below, the CQRC asks that CMS eliminate the duplicative face-to-face and related documentation, as well as the written order prior to delivery requirements established at 42 C.F.R. § 410.38 and reiterated in the LCDs. Instead for home oxygen therapy, CMS should rely upon a completed CMN when signed by the physician (ideally using an electronic data elements in the near future) along with the prescription (either verbal or written) as the primary documentation to establish medical necessity. For home respiratory therapy, CMS should rely upon the physician's prescriptions and the results of the sleep test, along with the verification of training by the supplier. Only if there is a suspicion of fraud should a Medicare contractor request subsequent documentation. While this subsequent documentation could include the medical record, CMS should also accept an attestation (written or electronic) from the prescriber answering the specific questions on which the contractor needs clarification to determine medical necessity. It should not be an opened-ended narrative that leaves the prescriber guessing as to what information is needed.

Second, we ask that the proof of delivery requirements be modified to allow for common sense exceptions to the basic requirement that the proof of delivery be obtained only at initial delivery. There should be alternative options for providing a proof of delivery if the initial document is lost or when a Medicare beneficiary actually began receiving home respiratory therapy prior to aging into Medicare.

Third, we also ask that CMS provide additional guidance to the Medicare contractors to avoid auditing the same patients multiple times using different dates of service, as well as prohibiting the application of new audit requirements to patients who began service prior to the implementation of the new policies, if those policies create new or modified documentation requirements.

Finally, we ask that CMS streamline the audit process and work with the industry to prevent duplication of audits because of the substantial number of contractors who are auditing home respiratory therapy suppliers under different Medicare program integrity projects.

B. CMS Should Use Its Discretionary Authority to Eliminate the Face-to-Face Examination and Written Order Prior to Delivery Requirements Prior, which Are the Sources for the Overly Burdensome Documentation Requirements for Home Respiratory Therapy Equipment.

1. The Secretary Has the Discretionary Authority to Eliminate the Face-to-Face Examination Requirement, as well as the Written Order Prior to Delivery, for Home Respiratory Therapy Equipment.

The current face-to-face and written order prior to delivery requirements place a substantial burden on patients and suppliers. It also increases Medicare spending and patient co-payment obligations without providing additional benefit to the program. While the Congress created a face-to-face requirement in the SSA, this statutory requirement only applies directly to power wheelchairs.[1] The other provisions of this section require the Secretary to "establish standards for clinical conditions for payment for covered items under this subsection."[2] In establishing these clinical conditions the Secretary:

> shall include the specification of types or classes of covered items that require, as a condition of payment under this subsection, a face-to-face examination of the individual by a physician (as defined in section 1861(r)), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5)) and a prescription for the item. [3]

While this section requires a face-to-face examination be one of the clinical conditions, the statute is silent as to the specific "types or classes of covered items" that are subject to this requirement. The Congress also instructed the Secretary as to how to prioritize establishing these clinical conditions, but again it did not specifically mandate that the face-to-face examination requirement be applied to home respiratory therapy equipment or supplies.

> In establishing the standards under this subparagraph, the Secretary shall first establish standards for those covered items for which the Secretary determines there has been a proliferation of use, consistent findings of charges for covered items that are not delivered, or consistent findings of falsification of documentation to provide for payment of such covered items under this part.[4]

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[1] *See* 42 U.S.C. § 1395m(a)(1)(E)(iv).
[2] *See id.* at § 1395m(a)(1)(E)(i).
[3] *See id.* at § 1395m(a)(1)(E)(ii).
[4] *See id.* at § 1395m(a)(1)(E)(iii).

Therefore, the Congress left it to the Secretary's discretion as to whether the face-to-face examination requirement should apply to covered items other than power wheelchairs.

Similarly, section 6407 of the ACA creates discretionary, not mandatory, authority when it comes to establishing a written order prior to delivery requirement. Specifically, the statute states:

> The Secretary is authorized to require, for specified covered items,[5] that payment may be made under this subsection with respect to the item only if a physician enrolled under section 1395cc(j) of this title or an eligible professional under section 1395w–4(k)(3)(B) of this title that is enrolled under section 1395cc(j) of this title has communicated to the supplier, before delivery of the item, a written order for the item.[6]

The use of the term "is authorized" is not the same as "shall." If the Congress had used the term "shall," then the requirement would be mandatory. It did not, so the Secretary has discretion when it comes to implementing this requirement. The discretion specifically relates to the specific items or services to which the Secretary decides to apply the written order prior to delivery.

If the Secretary exercises that discretion to require a written order prior to delivery, then he must:

> require that such an order be written pursuant to a physician, a physician assistant, a nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1395x(aa)(5) of this title) documenting such physician, physician assistant, practitioner, or specialist has had a face-to-face encounter (including through use of telehealth under subsection (m) and other than with respect to encounters that are incident to services involved) with the individual involved during the 6-month period preceding such written order, or other reasonable timeframe as determined by the Secretary.[7]

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[5]The term "specified covered items" as used in this provision is not defined in statute. While there is a definition of the term at paragraph (21), the use of this definition is limited to that paragraph by the text of subparagraphs (A) and (B). So, while this definition includes oxygen and oxygen equipment, it does not include other home respiratory therapies and is not applicable outside of paragraph (21). *See id.* at § 1395m(a)(21).

[6]*See id.* at § 1395m(a)(11)(B)(i).

[7]*See id.* at § 1395m(a)(11)(B)(ii).

As with the face-to-face requirement, the statute provides discretionary authority that allows the Secretary to implement the written order prior to delivery, but does not require it.

The Secretary implements these two statutory provisions at 42 C.F.R. § 410.38(g), establishing a face-to-face examination and a written order prior to delivery requirement. It is here,[8] not the statute, where the requirements for the face-to-face examination and the written order prior to delivery are applied to "oxygen and respiratory equipment."[9] Since the Secretary exercised discretion to place these requirements on home respiratory therapy equipment, he also has the authority to eliminate these requirements on home respiratory therapy.

2. The Face-to-Face Examination and Written Order Prior to Delivery Requirements Should Not Be Applied to Home Respiratory Therapy Equipment Because of Concerns of Overutilization and/or Fraud.

We appreciate that the Secretary may feel compelled to retain the face-to-face examination and/or written order prior to delivery requirements on home respiratory therapy equipment because the previous administration repeatedly asserted that these areas are ripe with fraud. However, these statements were an exaggeration of the actual problem bolstered by overly aggressive auditors that denied claims because of technical problems, misapplication of the law, or failure to read the documents submitted by suppliers. The audit process under the previous administration was a game of "gotcha" played to create a story of fraud and abuse when the problem was much smaller than the perception.

As we have noted, home respiratory therapy suppliers have a substantial favorable overturn rate that reinstates their payments when they challenge the denials before the ALJs. The Government Accountability Office (GAO) has ignored these outcomes in its reports on home respiratory therapy audits. In addition, the CERT reports support the experience of the CQRC companies. According to the 2016 CERT report, the home oxygen improper payment rate was 45 percent. Of that, 91.2 percent was due to missing documentation only 0.3 percent was due to the beneficiary not meeting the medical necessity requirements. A similar story is true for CPAP. The improper payment rate was 59.6 percent. Of this percentage, 85.2 percent was due to missing documentation, but only 0.6 percent was due to an actual lack of medical necessity.[10] <u>If CMS's own contractor acknowledges that nearly 100 percent of beneficiaries who are prescribed home respiratory therapy actually meet the medical necessity requirements, it is not clear why claims should be</u>

[8]See 77 Fed. Reg. 44722, 44796 (July 30, 2012).
[9]*See* 42 CFR § 410.38(g)(2)(ii)(3).
[10]Department of Health and Human Services (HHS), "The Supplementary Appendices for the Medicare Fee-for-Service 2016 Improper Payments Report" 21 (2016).

denied. The current overly technical and burdensome documentation requirements serve no purpose.

For CQRC members trying to meet them, these unnecessary requirements increase their costs by 40 percent or more. These costs relate to compliance personnel, staff to track down medical records, and lawyers and other consultants to defend claims. While the government has never released the cost it incurs by enforcing the documentation requirements, it must be substantial, especially given the hiring of additional ALJs in recent years to handle the backlog of appeals. Yet, as the CERT report shows, the benefit to the program is extremely limited. While the documentation requirements "catch" improper payments, they do not identify actual fraud or abuse of the system. That is why the current requirements are a game of "gotcha" rather than a well-balanced, effective approach to stopping fraud and abuse in the Medicare program.

Therefore, we ask that the Trump Administration look at the actual record and take into account (1) the overly burdensome nature of the documentation requirement; (2) the fact that prescribers – not suppliers – create the documents by which suppliers are judged; and (3) the broken audit process when evaluating the fraud and abuse problem in the area of home respiratory therapy equipment. We sincerely believe that if you do so, you will find that while there may be some fraud or abuse it is not at the scale asserted by the Obama Administration.

3. The Burdensome Documentation Requirements Stem from the Face-to-Face Examination and Written Order Prior to Delivery and Unnecessarily Layer on Existing Prescriber Visit and Prescription Requirements.

The face-to-face examination within the previous six months and the written order prior to delivery requirements should not be applied to home respiratory therapy equipment because there are other requirements that provide CMS with the information it needs to evaluate medical necessity. Prior to the Secretary using the discretion to apply the face-to-face examination and written order prior to delivery requirements, home oxygen therapy equipment (including when delivered through a continuous positive airway pressure or bilevel positive airway pressure device) was (and continues to be) governed by a national coverage determination (NCD 240.2) and local coverage determination (LCD 33797). Both of these documents already required physician visits and written prescriptions. Thus, the addition of the face-to-face examination and the written order prior to delivery created additional requirements that layered onto those that previously existed. Similar requirements existed for home sleep therapy in terms of required elements for physician prescriptions and sleep tests.

NCD 240.2 and LCD 33797 set forth the requirements for establishing medical necessity for home oxygen therapy quite clearly. NCD 240.2 requires medical documentation of the patients' need, which can be a written prescription by a physician who has seen the patient within the month of starting the therapy.[11] It must specify:

- A diagnosis of the disease requiring home use of oxygen;
- The oxygen flow rate; and
- An estimate of the frequency, duration of use (e.g., 2 liters per minute…12 hours per day), and duration of need (e.g., 6 months or lifetime).[12]

The prescriber must also describe the type of oxygen delivery system to be use.[13] "Initial claims for oxygen therapy must also include the results of a blood gas study that has been ordered and evaluated by the attending physician."[14]

The LCD states:

> Home oxygen therapy is reasonable and necessary only if all of the following conditions are met:
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> 1. The treating physician has determined that the beneficiary has a severe lung disease or hypoxia-related symptoms that might be expected to improve with oxygen therapy, and
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> 2. The beneficiary's blood gas study meets the criteria stated below, and
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> 3. The qualifying blood gas study was performed by a physician or by a qualified provider or supplier of laboratory services, and
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> 4. The qualifying blood gas study was obtained under the following conditions:
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> 1. If the qualifying blood gas study is performed during an inpatient hospital stay, the reported test must be the one obtained closest to, but no earlier than 2 days prior to the hospital discharge date, or
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> 2. If the qualifying blood gas study is not performed during an inpatient hospital stay, the reported test must be performed while the

[11] *See* NCD 240.2, § B.
[12] *Id.*
[13] *Id.*
[14] *Id.* at § C.

> beneficiary is in a chronic stable state – i.e., not during a period of acute illness or an exacerbation of their underlying disease, and
>
> 5. Alternative treatment measures have been tried or considered and deemed clinically ineffective.[15]

The LCD further explains that:

> All oxygen qualification testing must be performed in-person by a physician or other medical professional qualified to conduct oximetry testing. With the exception of overnight oximetry (see below), unsupervised or remotely supervised home testing does not qualify as a valid test for purposes of Medicare reimbursement of home oxygen and oxygen equipment.[16]

In addition, the LCD requires a Certificate of Medical Necessity (CMN). While this document is ignored in practice (unless it is missing[17]), it still serves as the only clear objective document that prescribers are able to clearly understand what information CMS requires them to provide. The CMN could be slightly modified to require the date of the treating physician visit; it already includes information about the prescription.

> 1. The blood gas study must be the most recent study obtained within 30 days prior to the Initial Date.
>
> 1. For situation 1, there is an exception to the 30-day test requirement for beneficiaries who were started on oxygen while enrolled in a Medicare HMO and transition to fee-for-service Medicare. For those beneficiaries, the blood gas study does not have to be obtained 30 days prior to the Initial Date, but must be the most recent qualifying test obtained while in the HMO.
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> 2. The beneficiary must be seen and evaluated by the treating **physician within 30 days** prior to the date of Initial Certification.[18]

The prescriber must sign the CMN. CMS allowed the CMN to stand in the place of the detailed written order as well, which remains part of the current LCD.[19]

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[15] *See* LCD 33797 at 3.
[16] *Id.* at 5.
[17] *See id.* at 9.
[18] *Id.* at 8 (*emphasis added)*.
[19] *Id.* at 18.

In a similar manner, the pre-ACA requirements for home sleep therapy required a physician-ordered sleep test interpreted by qualified physician.[20] A qualified physician must have:

1. Current certification in Sleep Medicine by the American Board of Sleep Medicine (ABSM); or,
2. Current subspecialty certification in Sleep Medicine by a member board of the American Board of Medical Specialties (ABMS); or,
3. Completed residency or fellowship training by an ABMS member board and has completed all the requirements for subspecialty certification in sleep medicine except the examination itself and only until the time of reporting of the first examination for which the physician is eligible; or,
4. Active staff membership of a sleep center or laboratory accredited by the American Academy of Sleep Medicine (AASM), Accreditation Commission for Health Care (ACHC), or The Joint Commission (TJC, formerly the Joint Commission on Accreditation of Healthcare Organizations – JCAHO). [21]

The results of this test require a patient met specific objective criteria:

1. The apnea-hypopnea index (AHI) or Respiratory Disturbance Index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events; or,
2. The AHI or RDI is greater than or equal to 5 and less than or equal to 14 events per hour with a minimum of 10 events and documentation of:
    a. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or,
    b. Hypertension, ischemic heart disease, or history of stroke.[22]

The physician must provide a dispensing order as well that includes:

- Description of the item
- Beneficiary's name
- Prescribing Physician's name
- Date of the order and the start date, if the start date is different from the date of the order
- Physician signature (if a written order) or supplier signature (if verbal order).[23]

[20]See, LCD: Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L33718) (sleep test requirements).
[21]*Id.*
[22]*Id.*
[23]PIM 5.2.2.

Face-to-Face Examination Requirement Request. For home oxygen therapy, the face-to-face requirement was added on top of the existing physician visit that had to be 30 days prior to the date of initial oxygen certification. CMS currently requires suppliers to have written documentation (*e.g.,* the medical notes) of the face-to-face examination in their files prior to delivering these items and has eliminated the option for a dispensing order (see below). The still required 30 day prior to the initial certification did not require the detailed level of prescriber-produced information and relied upon the physician attesting to the patient's need on the CMN.

For home sleep therapy, the face-to-face visit was also added upon the already existing requirement that a treating physician evaluate a patient for the device, order a sleep test (which had to be interpreted by a specifically qualified physician), and then write another order for the device. While it does not require a CMN, copies of the orders and the sleep test results were required.

Thus, the face-to-face examination requirement is problematic because of these onerous documentation requirements that are outside of the control of the supplier. There is no penalty if the prescriber does not produce the documentation; only the supplier is penalized by having the claim for supplying a legitimately prescribed item denied.

Additionally, prescribers are not told what must be in the medical record for an audit to consider it to "support" the prescription. While the Program Integrity Manual (PIM) describes the documentation requirements in terms of what the contractors must verify, it is vague. It states:

> The contractor shall verify that the face-to-face encounter documentation includes information supporting that the beneficiary was evaluated or treated for a condition that supports the DME item(s) ordered. If this information is not included, the contractor shall deny the claim. If the physician completed the written order before the face-to-face encounter, the contractor shall deny the claim.[24]

Thus, it is left to the contractor to determine what specific information establishes that the beneficiary was evaluated or treated for a condition that requires ordering the home respiratory therapy. This lack of clarity has created substantial implementation problems that usually result in contractors simply denying more and more claims, even if a prescriber provides medical notes in addition to the CMN and prescription.

[24] PIM 5.2.5.1

Therefore, we ask that home respiratory therapy equipment be removed from the list of DME subject to the face-to-face examination requirement. Instead, CMS should rely upon the CMN information and maintain the required physician visit 30 days prior to the date of initial certification (as added to the CMN). It should return to requiring the physician orders and appropriately administered sleep test results for home sleep therapy claims. Additionally, CMS should eliminate the requirement that the suppliers provide the prescribers' medical record for establishing medical necessity. A prescriber attestation of specific data required by CMS to establish medical necessity should be sufficient to establish medical necessity.

Written Order Prior to Delivery Requirement Request. The previous requirements also mandated a prescription. However, these requirements recognized that oxygen, in particular, may need to be dispensed urgently and allows for verbal or written orders. Because the prescriber included test results, prescribing information, and signed the CMN, the verbal order had to be documented and kept on file. It had to contain the following:

- Description of the item
- Beneficiary's name
- Prescribing Physician's name
- Date of the order and the start date, if the start date is different from the date of the order
- Physician signature (if a written order) or supplier signature (if verbal order)

For the "Date of the order" described above, use the date the supplier is contacted by the physician (for verbal orders) or the date entered by the physician (for written dispensing orders).[25]

Previous law still required a written detailed order, but since the CMN contained the same information and was also signed and dated by a physician, CMS recognized the CMN as the detailed written order.[26]

As noted already, for home sleep therapy, a dispensing order containing the same bulleted information required for home oxygen therapy was required.

The primary issue with the written order prior to delivery is that all of this information must be handed off to the supplier before the supplier can fill the prescription. This can be extremely onerous and delay patient care. For example, if the prescribing physician prescribes home oxygen therapy equipment verbally and

[25]LCD at 14.
[26]*Id.* at 18.

then indicates that the patient may be discharged from the hospital, the patient cannot actually be released until the supplier has the detailed written order in hand and signed by the physician. Since the physician is not penalized for not providing the order, there is no incentive for the physician to complete this paperwork on the timeline CMS has set forth. This means that a patient's discharge can be substantially delayed. Contractors are currently delaying patient hospital discharges even if only one element, such as the physician's NPI, is missing. This situation is absurd and costly. There is no evidence that substituting this new written order prior to dispensing requirement has reduced fraud or abuse of the Medicare program when compared to the program when the CMN functioned as the detailed written order and could be obtained soon after the equipment was dispensed. What the written order prior to dispensing does is create a bureaucratic nightmare for suppliers, hospitals, and patients trying to deliver care in the most effective and efficient way possible.

Therefore, we ask that CMS eliminate home respiratory therapy equipment from the list of items subject to the written order prior to delivery and return to using the CMN for home oxygen therapy or the prescriptions and sleep test results for home respiratory therapy (or specific electronic structured data submitted by a prescriber) to support medical necessity for such equipment.

4. No Evidence Indicated that the Previous Physician Visit and Prescription Requirements Were Flawed.

There is no evidence that the previous system was flawed. As the CERT report and CMS note, the patients who are receiving home respiratory therapies in fact need the therapies. The error rates are due to suppliers not being able to meet the onerous documentation requirements. These failures are often because suppliers are not permitted to submit an alternative document when an original does not exist; prescribers do not provide the "magic words" contractors are looking for to confirm the medical need; or contractors fail to read the record correctly. If CMS and its contractors were to focus on claims filed using stolen Medicare beneficiary numbers or for deceased beneficiaries or similar fraudulent behavior, the error rates would fall and the prosecution of the fraudulent and abusive "supplier" would increase.

C. CMS Should Modify the Proof of Delivery Requirement to Allow for Alternative Documentation Options.

While eliminating the overly burdensome medical necessity document requirements created under the face-to-face and the written order prior to delivery requirements address many of overly burdensome aspects of current requirements, the limited proof of delivery requirements also create an unnecessary burden on suppliers and impact beneficiaries. Contractors refuse to accept anything other than

an original proof of delivery. Thus, we ask that the proof of delivery requirements be modified to allow for common sense exceptions to the basic requirement that the proof of delivery be obtained at initial delivery.[27] While the instructions in the PIM suggest that proof of delivery can be established by a recently eligible beneficiary (or appropriate representative) who has already been receiving home oxygen therapy signing a delivery ticket, which is dated with the first day of the first rental month, in practice contractors do not accept such documents.[28] We ask that CMS provide clear guidance allowing for alternative options for providing a proof of delivery if the initial document is lost or when a Medicare beneficiary actually began receiving home respiratory therapy prior to aging into Medicare.

D. CMS Should Stop Contractors from Auditing the Same Patients Using Different Dates of Service.

Third, the CQRC asks that CMS provide additional guidance to the Medicare contractors to avoid auditing the same patients multiple times using different dates of service, as well as prohibit the application of new audit requirements to patients who began service prior to the implementation of the new policies, if those policies create new or modified documentation requirements. Despite the success of the First Claims Audit, home respiratory therapy suppliers continue to experience multiple audits on the same patient for different dates of service. Once a contractor has accepted the documentation establishing medical necessity for a patient, it should not continue to audit that patient. Similarly, contractors should not retroactively apply new requirements that suppliers and prescribers did not know would be required at the time the beneficiary was prescribed. These current practices are incredibly burdensome and unfair in their implementation.

E. CMS Should Streamline the Audit Process to Avoid Duplicative Audits of the Same Patient and Same Claims.

Finally, we ask that CMS streamline the audit process and work with the industry to prevent duplication of audits because of the four different types of contractors (Medicare Administrative Contractors (MACs), Zone Program Integrity Contractors (ZPICs), Recovery Audit Contractors (RACs), and Comprehensive Error Rate Testing (CERT) contractors) who are auditing home respiratory therapy suppliers using three different types of audits. These multiple audits are extremely burdensome and confusing because while a set of documents for a specific beneficiary may be cleared in one audit process it may be denied in another. The inconsistencies do not make sense. We understand that these requirements are mostly statutory, but we would like to work with CMS to find ways to streamline these various audit tracks to make less burdensome.

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[27] PIM, § 5.8.
[28] *Id.*

III. Conclusion

The CQRC appreciates your efforts to reduce overly burdensome regulations that interfere with the ability of home respiratory therapy suppliers to provide quality home care to beneficiaries who require life-sustaining home oxygen and sleep therapies. We would welcome the opportunity to talk with your staff in more detail about our suggestions. Please contact me at (202) 534-1773 or klester@lesterhealthlaw.com if you have questions or would like to discuss these recommendations in more detail.

Sincerely,

Kathy Lester

Kathy Lester
Executive Director
Council for Quality Respiratory Care

cc: Melanie Combs-Dyer, Director, Provider Compliance Group