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Open Letter to **Centers for Medicare & Medicaid Services**

**Re: CMS Guidance Recommends Monitoring of All Patients Receiving Opioids**

The Physician-Patient Alliance for Health & Safety would like to applaud the Centers for Medicare & Medicaid Services (CMS) for issuing its March 14, 2014 guidance, "[Requirements for Hospital Medication Administration, Particularly Intravenous \(IV\) Medications and Post-Operative Care of Patients Receiving IV Opioids](#)".

This guidance recommends "at a minimum" [page 19] that hospitals "have adequate provisions for immediate post-operative care, to emphasize the need for post-operative monitoring of patients receiving IV opioid medications, regardless of where they are in the hospital." [page 1]

In addition and more importantly, the CMS guidance necessitates monitoring for all patients receiving opioids when in hospital:

*Narcotic medications, such as opioids, are often used to control pain but also have a sedating effect. Patients can become overly sedated and suffer respiratory depression or arrest, which can be fatal. Timely assessment and appropriate monitoring is essential in all hospital settings in which opioids are administered, to permit intervention to counteract respiratory depression should it occur. [page 15]*

This CMS guidance provides increased vigilance to patients receiving opioids, particularly those patients receiving opioids postoperatively. CMS explains the reason behind the issue for this guidance:

*Each year, serious adverse events, including fatalities, associated with the use of IV opioid medications occur in hospitals. Opioid-induced respiratory depression has resulted in patient deaths that might have been prevented with appropriate risk assessment for adverse events as well as frequent monitoring of the patient's respiration rate, oxygen and sedation levels<sup>2</sup>. Hospital patients on IV opioids may be placed in units where vital signs and other monitoring typically is not performed as frequently as in post-anesthesia recovery or intensive care units, increasing the risk that patients may develop respiratory compromise that is not immediately recognized and treated. [page 2]*

Continuous electronic monitoring of patients is the standard of care for patients in operating rooms. As the standards for the American Society of Anesthesiologists (ASA) [state](#):

*During all anesthetics, the patient's oxygenation, ventilation, circulation and temperature shall be continually evaluated.*

Although there are many ways to monitor patients, monitoring continuously with pulse oximetry for oxygenation and capnography for adequacy of ventilation are the two airflow monitors that the ASA currently recommends. Continuous monitoring using the most advanced and approved available technology for monitoring oxygenation and breathing quality must be encouraged and adopted as expeditiously as possible.

To achieve better patient safety, the CMS guidance reminds us of three keys for success:

#### #1 - Basic Safe Practices for Medication Administration

The CMS guidance recommends basic safe practices for medication administration. As it states: *The hospital's policies and procedures must reflect accepted standards of practice that require the following be confirmed prior to each administration of medication (often referred to as the "five rights" of medication administration practice).* [page 10]

This means ensuring that these five rights occur:

The **Right Patient**  
receives the **Right Medication**  
and the **Right Dose**  
through the **Right Route**  
at the **Right Time**

Although the five rights may seem simple requirements to follow, a [survey](#) that PPAHS conducted among almost 168 hospitals across 40 states shows that hospitals are inconsistently applying these safe medication practices.

#### #2 - Assessment/Monitoring of Patients Receiving Medications

The CMS guidance cautions that patients must be carefully assessed:

*Patients must be carefully monitored to determine whether the medication results in the therapeutically intended benefit, and to allow for early identification of adverse effects and timely initiation of appropriate corrective action.* [page 14]

This assessment must not just include periodic nursing assessment, as was last year proposed in the [CMS quality measure](#) (#3040) that patients receiving patient-controlled analgesia be "documented" at least once every 2.5 hours for "respiratory rate, sedation score and pulse oximetry."



In speaking about measure #3040 which would have mandated periodic nursing assessments, Robert Stoelting, MD (President, Anesthesia Patient Safety Foundation) [stated](#):

*the conclusions and recommendations of APSF are that intermittent 'spot checks' of oxygenation (pulse oximetry) and ventilation (nursing assessment) are not adequate for reliably recognizing clinically significant evolving drug-induced respiratory depression in the postoperative period. For the CMS measure to better ensure patient safety, APSF recommends that monitoring be continuous and not intermittent, and that continuous electronic monitoring with both pulse oximetry for oxygenation and capnography for the adequacy of ventilation be considered for all patients.*

This nursing assessment must be supplemented with a technological safety net. Intermittent nursing assessment of patients in simultaneous combination with continuous electronic monitoring will improve patient safety. As Juliana Morath, RN, MS (then Chief Quality and Safety Officer, Vanderbilt University Medical Center; now CEO, Hospital Quality Institute, California Hospital Association) [emphasized](#):

*Human vigilance is required but insufficient, continuous electronic monitoring needs to be there to support and back up nurses, and allow them to visit a patient while monitors are continuously assessing other patients for various physiological parameters (such as, oxygenation with pulse oximeter and adequacy of ventilation with capnography).*

### #3 - Patient Education

The CMS guidance encourages engaging patients and their families in improving patient safety:







*The assessment and monitoring process must be explained to the patient and/or the patient's representative, to communicate the rationale for vigilant monitoring, including that it might be necessary to awaken the patient in order to assess effects of the medications. In addition, hospitals are encouraged to educate the patient and his/her representative and/or family members about notifying nursing staff promptly when there is difficulty breathing or other changes that might be a reaction to medication. [page 21]*

What can patients and their families do?

On Appendix "A", we offer five essential of opioid safety, which are an adaptation of [Amanda's Four Essentials for Safety](#) developed by Brian and Cindy Abbiehl who tragically lost their 18 year old daughter, [Amanda](#), to opioid-induced respiratory depression.



Although we recognize that hospitals may have difficulty and experience challenges in implementing this CMS guidance, we ask clinicians and hospital executives to remember that patients and their families have entrusted their safety and care in your hands. Just a small fraction of such patients are shown below with links to their stories:

 <p><b>Amanda Abbiehl</b> 18-year old, admitted for "severe strep throat" unmonitored use of PCA <a href="http://promisetoamanda.org/?page_id=32">http://promisetoamanda.org/?page_id=32</a></p>	 <p><b>Robert Goode</b> unmonitored use of PCA following hiatal hernia surgery <a href="http://community.advanceweb.com/blogs/nurses3/archive/2013/07/03/nursing-spot-checks-for-patient-safety-a-nurse-s-perspective.aspx">http://community.advanceweb.com/blogs/nurses3/archive/2013/07/03/nursing-spot-checks-for-patient-safety-a-nurse-s-perspective.aspx</a></p>	 <p><b>Louise Batz</b> unmonitored use of PCA following knee replacement surgery <a href="http://ppahs.org/2012/01/13/guest-post-monitoring-can-prevent-errors-with-patient-controlled-analgesia/">http://ppahs.org/2012/01/13/guest-post-monitoring-can-prevent-errors-with-patient-controlled-analgesia/</a></p>
 <p><b>John LaChance</b> unmonitored obstructive sleep apnea patient administered opioids <a href="https://www.youtube.com/watch?v=dH9agqZRDxw">https://www.youtube.com/watch?v=dH9agqZRDxw</a></p>	 <p><b>Tyler Ireland</b> unmonitored PCA after surgery for collapsed lung</p>	 <p><b>Justin Micalizzi</b> unmonitored PCA after surgery for surgery to incise and drain a swollen ankle <a href="http://ppahs.org/2011/08/18/would-monitoring-have-saved-justin-micalizzi/">http://ppahs.org/2011/08/18/would-monitoring-have-saved-justin-micalizzi/</a></p>

Best regards,

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Executive Director  
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Patricia LaChance  
Wife of [John Michael LaChance](#)

Michèle G. Curtis, MD, MPH, MML  
CeeShell Consulting, editor of "Glass' Office Gynecology"

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Chairman  
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## Appendix "A"

### Five Essentials of Opioid Safety

<p><b>Five Essentials of Opioid Safety</b></p> 	<p>1. Ensure these five rights occur: The <b>Right Patient</b> receives the <b>Right Medication</b> and the <b>Right Dose</b> through the <b>Right Route</b> at the <b>Right Time</b></p> <div style="text-align: center;">  <p style="font-size: small;">Source: <a href="https://en.wikipedia.org/wiki/Dissemination_of_Information_Articles">https://en.wikipedia.org/wiki/Dissemination_of_Information_Articles</a></p> </div> 
<div style="display: flex; align-items: center;">  <div style="margin-left: 20px;"> <p>2. Ensure patients and their families understand the use of opioids to manage their pain have risks. Managing these risks are essential to preventing opioid-related deaths or adverse events. For example, patients on PCA pumps should understand:</p> <ul style="list-style-type: none"> <li>• PCA pumps deliver a powerful narcotic</li> <li>• There should be no PCA by proxy.</li> </ul> </div> </div> <p style="font-size: x-small; margin-top: 5px;">Source: <a href="http://blog.merckhealthcare.com/2014/05/05/what-is-a-pca-pump-and-how-to-use-it-properly/">http://blog.merckhealthcare.com/2014/05/05/what-is-a-pca-pump-and-how-to-use-it-properly/</a></p> 	<p>3. Make sure patients/families understand why they must be monitored:</p> <ul style="list-style-type: none"> <li>• oximetry on finger</li> <li>• capnography cannula on nose</li> </ul> <div style="text-align: center; margin-top: 10px;">  </div> 
<p>4. Educate patients and their families about monitor readouts:</p> <div style="display: flex; align-items: center; margin-top: 10px;">  <div style="margin-left: 10px;"> <p style="font-size: x-small;">Figure 1. A normal capnography waveform.</p> <p>Normal EtCO<sub>2</sub> values:</p> <ul style="list-style-type: none"> <li>• 80 to 48 mmHG</li> </ul> </div> </div> <div style="text-align: center; margin-top: 10px;">  </div> <ul style="list-style-type: none"> <li>• Normal blood oxygen saturation level = 94% to 99%.</li> <li>• Mild respiratory disease= 90% or above.</li> <li>• Supplementary oxygen needed = less than 90%</li> </ul> 	<p>5. Educate patients why alarms sound and what to do when they do sound.</p> <div style="text-align: center; margin-top: 10px;">  <p style="font-size: x-small;">Example of patient surveillance monitoring (shown that used by Wesley Medical Center, Hattiesburg, MO)</p> </div> 