THE PATIENT SAFETY INSIDER
SPRING 2019 NEWSLETTER

An inside look at patient safety resources, best practices, and industry happenings across the healthcare continuum from the Center for Patient Safety

VAIL HEALTH’S JOURNEY TO A SAFETY CULTURE

Erin Satsky and Brittany Clymer
Vail Health
The Center for Patient Safety Launches EMS Patient Safety Leadership
This workshop will teach EMS leaders how to enhance their safety culture and identify and learn from medical errors.

NEW NEWS!
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Center for Patient Safety

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Center for Patient Safety

ABOUT THE CENTER:
The Center for Patient Safety was founded in 2005, as a private, non-profit corporation to serve as a leader to fulfill its vision of a healthcare environment safe for all patients and healthcare providers.

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NOTE: Some articles contained within this newsletter may reference materials available to Center for Patient Safety PSO participants only. If you have questions about any Center resources or articles within this newsletter, please contact the Center for Patient Safety at info@centerforpatientsafety.org or call 573.636.1014.

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A LETTER FROM THE EXECUTIVE DIRECTOR

I am excited to announce that the Center for Patient Safety (CPS) is experiencing a significant period of growth, reaching new provider groups in many new areas across the nation as well as the world. We are grateful to each new client and partner that extends an offering to support our work and promote our mission: reducing preventable harm.

Our new services include programs that are integral to patient safety improvement but where we discovered inefficient program execution within healthcare organizations. To address the gaps, CPS developed customizable onsite training programs, virtual support services, and enhanced program offerings that are administered individually or together as a larger initiative. We’ve also launched the EMSForward360, a follow up to our EMSForward campaign and recently developed a HealthcareForward campaign to raise awareness across the care spectrum.

With the diversity of our team members, CPS is contacted regularly to attend speaking engagements around the world, offering thought-leadership on topics dedicated to patient safety, culture improvement, and effective leadership. Our team has addressed pharmacists, healthcare attorneys, patient safety organizations (PSOs), doctors, emergency medical service providers, home care and hospice providers, hospitals, health systems, nursing homes, medical offices, state-based agencies, and more.

I’d like to recognize the Center’s founding members, Primaris and the Missouri State Medical Association, and our board members. These organizations and groups of individuals support our mission daily and have proven to be the foundation for our success. We would not be where we are without these amazing groups that volunteer their time and energy to support so many in the cause to reduce preventable harm in healthcare. Together, we will make a difference.

As a non-profit organization, CPS intentionally keeps costs low to encourage participation, but still charges minimal amounts so we can keep our lights on. However, we continue to provide many freely available resources and tools. Please help us continue to provide these valued services by considering a donation to CPS. There are three ways to join the effort to spread patient safety throughout your healthcare community: individual donation or sponsorship, organizational donation or sponsorship. Your contribution supports the Center for Patient Safety’s efforts to provide ongoing resources, education, training and other activities to reduce medical errors and protect the patients in our communities. The Center for Patient Safety is an independent, not-for-profit, 501(c)3 corporation; therefore, your donation may qualify as a tax deduction.

You can donate any amount you are comfortable with, any amount is appreciated. Click here to donate.

ALEX CHRISTGEN, CPPS, CPHQ
EXECUTIVE DIRECTOR

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EXECUTIVE DIRECTOR

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Good News from CMS Region 6

Over the last few months, PSOs, providers and provider associations have been fighting for the Patient Safety and Quality Improvement Act (PSQIA) protections of hospitals in CMS Region 6. State surveyors had demanded access to patient safety work product (PSWP), threatening termination of Medicare participation if they did not get it. The final outcome is very favorable to PSO participants and is outlined in detail below. The following information was provided by Chicago attorney Michael Callahan, one of the most active PSO law experts. His summary outlines the great outcome, but also lays a path for successful advocacy in this sort of situation.

Background:

Last year, state surveyors acting on behalf of CMS Region 6 conducted Federal surveys at four separate health care facilities located in Texas, New Mexico and Oklahoma. Each of these facilities contracted with a PSO. During the on-site investigation, the surveyors requested numerous documents to determine whether the facility was in compliance with the Medicare Conditions of Participation, including information which the facilities identified as PSWP. Despite efforts to inform the surveyors that the requested information was privileged under the Patient Safety Act, each facility received a nearly identical letter from the state surveyors...informing them that their refusal to provide the documents would result in the termination of their Medicare eligibility. These threats were made even though the facilities offered to cooperate with the investigation and to provide the surveyors with non-privileged information which they believed would demonstrate their compliance with the CoPs and QAPI. One surveyor, in response to one of the facility’s assertion of the privilege protections, stated that they were “entitled to see anything they wanted” in carrying out their legal authority. Because none of the hospitals could afford to lose their Medicare eligibility, each of them turned over the privileged materials.

Not surprisingly, these threats caused great concern because the apparent position of CMS Region 6, as communicated through the state surveyors, was at odds with a previously stated position of CMS in 2013 along with the HHS Guidance Regarding Patient Safety Work Product and Providers’ External Obligations issued on May 24, 2016, that CMS and other federal and state regulators “should not demand PSWP from providers or PSOs” and that PSWP “may not be used to satisfy external obligations.”

...[T]he Federation of American Hospitals, the Texas Hospital Association, the Dallas-Fort Worth Hospital Council and the New Mexico Hospital Association agreed to work with these several Region 6 health systems. Rather than approach Main CMS in Baltimore, the group decided that they should reach out directly to representatives at Region 6.

A joint letter from the associations...to both the Deputy Consortium Administrator for Dallas/Atlanta and the Deputy Regional Administrator requested a meeting...[and] described the circumstances at the three facilities. [It also shared] the providers’ communications with the surveyors to demonstrate each of the hospital’s participation in a PSO... Region 6 agreed to a meeting which took place on Thursday, March 7th in their Dallas office.

To help facilitate the meeting, the associations sent five questions to Region 6 in advance which essentially were designed to understand the basis for its position that the refusal to turn over PSWP would lead to their termination from Medicare. In addition, they asked why Region 6 was taking a position which was contrary to HHS and CMS published statement that Medicare facilities were not required to turn over PSWP although were otherwise obligated to demonstrate compliance with the CoPs and other regulatory requirements.

After introductions were made, and to the great relief of the trade associations, the first statement made by one of the Region 6 administrators was that “CMS does not require facilities to turn over PSWP” during a Federal survey. Over the course of the next 40 minutes, Region 6’s representations can be summarized as follows:

A. Region 6 Representations

1. Region 6 has trained the state surveyors in all 5 states to not require facilities to turn over PSWP. An example was given when, on one occasion, Region 6 advised a state surveyor that they could not request PSWP during an on-site survey.

2. While facilities are otherwise expected to disclose non-privileged information to establish compliance with the Medicare CoPs, the failure to do so would likely result in a citation but not termination from the Medicare program.

3. The threatening letters which the three facilities received were based on a template which was prepared by Region 6 and distributed to all state surveyors to more directly apply to a situation when a facility refuses to give state surveyors access in order for them to contact a survey.

4. The letters should not have been issued and were not intended to address a situation in which a facility declines to turn over PSWP.

5. Had either the surveyors or any of the facilities contacted Region 6, they would have been advised that PSWP does not have to be disclosed. No such calls were made.

B. Region 6 Commitments

1. Region 6 is going to retrain all of their state surveyors that a refusal to turn over PSWP is not just cause for terminating a facility’s Medicare eligibility or for even making a threat of termination.

2. The template letter will be revised.

3. Region 6 recommended, and the trade association representatives agreed, that all of the parties collaborate to prepare an educational program for Medicare facilities. The likely topics include:

   a. The role of CMS in Federal surveys
   b. The responsibilities of Medicare facilities under the CoPs
   c. The fact that facilities are not required to turn over PSWP but must otherwise demonstrate compliance with the CoPs
   d. Facilities should be prepared to establish that they participate in a PSO and that the documents requested are PSWP.
   e. Facilities should feel comfortable in contacting Region 6 when disputes arise during a survey.

4. It was further recommended that the respective State Departments of Health in all five states be involved with the program so that there is consistency in how state and federal surveys are conducted.

C. Take-Aways and Recommendations

...[I]t is certainly possible that hospitals and other facilities participating in a PSO could face similar demands for PSWP as well as termination threats. ...[L]isted below are some take away points and recommendations to consider:

1. CMS does not require facilities to turn over PSWP. When faced with a state surveyor demanding PSWP, a facility should do the following:
EVENT CALENDAR

APRIL

Learning Series Webinar - Chronic Obstructive Pulmonary Disease
April 10  |  12:00 pm - 12:30 pm CDT
REGISTER NOW

EMS Patient Safety Leadership Workshop
April 24  |  Uncasville, CT
REGISTER NOW

Laerdal Simulation User Network (SUN) Conference
April 25 - April 26  |  Uncasville, CT
REGISTER NOW

MAY

Learning Series Webinar - 5 of 12
More information Coming Soon!

Patient Safety Organization User Day
May 1  |  Blue Springs, MO
REGISTER NOW

2019 Missouri Pharmacy Patient Safety Conference
May 9  |  Columbia, MO  |  Available to Missouri Board of Pharmacy Licensees/Registrants ONLY
REGISTER NOW

Michigan Association of Ambulance Services – Boot Camp
May 10  |  Boyne Mountain Resort  |  Boyne Falls, MI

25th Annual Trends in Trauma
May 29 - May 30  |  St. Louis, MO

We Want Your Feedback!
Help us, help you! Please take our short Participation Survey to help us better serve your organization in the future.

LEARN MORE

The learning series is a monthly webinar hosted by CPS. Each webinar will focus on a different area of patient safety and will feature expert guest speakers to provide first-hand patient safety knowledge, lessons learned and more.

As always, feel free to contact CPS if you have any questions.

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a. Remind them that CMS does not require facilities to disclose PSWP but be prepared to establish that the facility is in a PSO and that the information sought is indeed PSWP. This can be demonstrated by showing them, for example, a copy of the PSO member agreement, a copy of your PSES policy, etc. Obviously, you should not let them see the PSWP or a copy of the PSWP.

b. Request that the surveyor contact the applicable CMS regional office and administrator.

c. Contact the CMS regional administrator directly.

d. Never deny access to the surveyor. Be prepared to disclose non-privileged information to establish compliance. (Remember, CPS has always advised its participants that an action plan resulting from protected work is not protected and can be shared.)

A final CPS recommendation: If disclosure of PSWP appears to be the only option to demonstrate COP compliance, there are options to consider:

- Information that was not developed in the PSES and has not been reported to the PSO may be dropped out. If you have questions about this option, contact CPS.
- There also is a written authorization disclosure exception that allows the disclosure of PSWP if all providers identified in the PSWP agree to the disclosure in writing.
- Work that is protected can be reproduced outside the PSES.

REMIND THEM THAT CMS DOES NOT REQUIRE FACILITIES TO DISCLOSE PSWP BUT BE PREPARED TO ESTABLISH THAT THE FACILITY IS IN A PSO AND THAT THE INFORMATION SOUGHT IS INDEED PSWP. THIS CAN BE DEMONSTRATED BY SHOWING THEM, FOR EXAMPLE, A COPY OF THE PSO MEMBER AGREEMENT, A COPY OF YOUR PSES POLICY, ETC. OBVIOUSLY, YOU SHOULD NOT LET THEM SEE THE PSWP OR A COPY OF THE PSWP.

b. REQUEST THAT THE SURVEYOR CONTACT THE APPLICABLE CMS REGIONAL OFFICE AND ADMINISTRATOR.

c. CONTACT THE CMS REGIONAL ADMINISTRATOR DIRECTLY.

d. NEVER DENY ACCESS TO THE SURVEYOR. BE PREPARED TO DISCLOSE NON-PRIVILEGED INFORMATION TO ESTABLISH COMPLIANCE. (REMEMBER, CPS HAS ALWAYS ADVISED ITS PARTICIPANTS THAT AN ACTION PLAN RESULTING FROM PROTECTED WORK IS NOT PROTECTED AND CAN BE SHARED.)

A FINAL CPS RECOMMENDATION: IF DISCLOSURE OF PSWP APPEARS TO BE THE ONLY OPTION TO DEMONSTRATE COP COMPLIANCE, THERE ARE OPTIONS TO CONSIDER:

- INFORMATION THAT WAS NOT DEVELOPED IN THE PSES AND HAS NOT BEEN REPORTED TO THE PSO MAY BE DROPPED OUT. IF YOU HAVE QUESTIONS ABOUT THIS OPTION, CONTACT CPS.
- THERE ALSO IS A WRITTEN AUTHORIZATION DISCLOSURE EXCEPTION THAT ALLOWS THE DISCLOSURE OF PSWP IF ALL PROVIDERS IDENTIFIED IN THE PSWP AGREE TO THE DISCLOSURE IN WRITING.
- WORK THAT IS PROTECTED CAN BE REPRODUCED OUTSIDE THE PSES.

WE WANT YOUR FEEDBACK!
HELP US, HELP YOU! PLEASE TAKE OUR SHORT PARTICIPATION SURVEY TO HELP US BETTER SERVE YOUR ORGANIZATION IN THE FUTURE.

LEARN MORE
Erin Satsky and Brittany Clymer
Vail Health

Vail Health is a 56-bed community hospital serving patients and guests from Eagle County, Colorado and around the world. In addition, a wide array of services and access points are provided across nine towns in two counties including clinics, urgent care centers and physical therapy centers.

“Our mission to ‘provide superior health services with compassion and exceptional outcomes’ drives everything our employees and physician do,” explained Vail Health’s Patient Advocate Brittany Clymer. Supporting this mission are six values, which have identified performance goals, and patient safety is the first listed value.

The patient safety journey began many years ago, focusing on process standardization and improvements that positively impact patient outcomes. In 2012, the first patient safety survey was administered, seeking feedback from employees and physicians. What sets Vail Health’s process apart from many other organizations is that they ask non-clinical staff to complete the survey. “While this approach has been a challenge for so many organizations, Vail Health has successfully boosted participation and culture improvement opportunities in non-clinical areas. They have found a way to communicate meaningful patient safety objectives across the entire organization,” said Alex Christgen, Executive Director, Center for Patient Safety (CPS). Vail Health believes that even though these individuals do not “touch” the patient, the work they do supports the exceptional outcomes that are required to fulfill its mission. Managers discuss the survey results with their employees, determining goals to support the organization’s overall goals. Weakest areas are trended annually to implement improvements and record progress.

To help support safety improvement, a formal Just Culture program and daily safety huddles have been implemented organization-wide. In addition, the organization continues to grow their shared governance structure and work toward their goal of Pathway to Excellence designation, which has been proven to impact patient safety.

Improvement work is not complete at Vail Health – they will continue to use the patient safety surveys to guide improvements to support exceptional patient outcomes.

“Safety is not just something we do; it’s how we do what we do. As leaders, we monitor safety reporting to find areas of potential risk, make a plan to address those areas, execute on that plan, continue to monitor outcomes of actions and course-correct as needed. Last year, we noticed an increase in falls within a three-month period. Upon investigation, we realized there was a pattern associated with each of these reported events and that each of the events involved a post-operative patient after the same surgery. Digging deeper, we found the anesthesia protocol for this procedure had recently changed. We gathered the interdisciplinary team, discussed our findings, and the anesthesia protocol was adjusted accordingly. We have not had a single fall in the last six months since that time. Patient safety is the highest priority at Vail Health. Keeping patients safe is a team effort and through appropriate monitoring and intervention, our team was able to improve the safety of our patients.”

Nico Brown, PT, MPT, FACHE
Senior Vice President, Howard Head Sports Medicine Operations and Vail Health Total Joint Care

VISIT vailhealth.org FOR MORE INFORMATION
Over the last few years, there has been an increased focus on the issue of maternal mortality in the U.S. From 1990-2015, this rate in the U.S. rose significantly despite a decrease in that same number among most other developed countries in the world. In fact, out of 183 countries that reported data, only 12 had an increase in their maternal mortality rate and the proud list, in addition to the U.S., included such countries as North Korea, Zimbabwe, Venezuela and the Bahamas.

Fortunately, over the last few years, this problem has been identified by such organizations as the American College of Obstetrics & Gynecology (ACOG) and the American Hospital Association and is now getting more attention. One of the earlier collaborative efforts to reduce maternal mortality is a group called the California Maternal Quality Care Collaborative, and they have been pioneers in the development of the gold standard to spearhead this problem. Since that time, many organizations in several states have become more proactive in these initiatives and are actually starting to make some impact. Ultimately, care bundles have been created for these situations with the goal of disseminating them to all hospitals where obstetric services are provided. In addition, algorithms have been created and recommendations have been made as to when and in what situations patients should be transferred to a higher level of care. One of these developments is the severe hypertension algorithms which clearly define timing for specific medication dosages. Other improvements include the QBL (quantitative blood loss) concept instead of estimated blood loss, and massive transfusion protocols which have been developed.

In order to adopt these new practices, massive education of staff and physicians must occur to help them understand the processes and to hardwire the changes into the culture of the organization. Some additive and very effective techniques include such things as team training and multidisciplinary simulation sessions which have become very commonplace in OB units.

It is imperative for every facility which performs obstetric services to become very familiar with these new, life-saving approaches. Only when these changes become the rule rather than the exception will we make a significant impact in the reduction of maternal mortality in the U.S.

ABOUT THE AUTHOR

Dr. Handler is the chief medical officer for Amita Health Alexian Brothers Medical Center and Amita Health St. Alexius Medical Center in suburban Chicago, IL. He is also the medical director for the Center for Patient Safety. As chief medical officer, Dr. Handler serves as liaison between the organized medical staff and administration, which advances the clinical practice of medicine for the campuses. He previously served as VRMA/chief medical officer for SSM St. Joseph Hospital Lake St. Louis in Lake St. Louis, MO from 2007 through 2017.

Dr. Handler has been a physician in the state of Missouri since 1985. He operated a private Obstetrics and Gynecology practice in suburban St. Louis from 1989 through 2007. Dr. Handler also served as house obstetrician from 2001 through 2017 in SSM hospitals and is board certified in obstetrics and gynecology.

Deadly Deliveries

Insight Into Maternal Mortality

Michael Handler, MD, MMM, FAAPL
Center for Patient Safety Medical Director

The U.S. has the highest maternal death rate among the world’s developed nations.

Alison Young, Deadly Deliveries, USA Today, March 6, 2019

At least 60 percent of maternal deaths are preventable.

Rachel Jones, American Women are Still Dying at Alarming Rates While Giving Birth, National Geographic, December 13, 2018

About 700 women die each year in the U.S. as a result of pregnancy or delivery complications.

Pregnancy - Related Deaths, Centers for Disease Control and Prevention, February 26, 2019


Prevention, February 26, 2019


While Giving Birth, National Geographic, December 13, 2018


While Giving Birth, National Geographic, December 13, 2018

Preview of 2018 Annual Report

CPS has received an increase of 6,675 events since 2017 with 79 organizations reporting. The majority of reports (excluding the "Other" category) fall into the Medication and Fall event categories. These event types are the most frequently reported every year. CPS is also receiving an increase of reports that are no harm, near miss or unsafe conditions. This suggests organizations are becoming more comfortable reporting to a PSO. It should not be assumed that more events are occurring, but rather the culture paradigm shift is occurring which reflects a more transparent industry. PSO participation continues to grow nationally. The aggregate learnings identify industry opportunities to reduce preventable harm. CPS issued watches and alerts in 2018 based on the PSO data and also events reported by participating organizations.

Respiratory Compromise
Violence against Healthcare Workers
Look Alike Sound Alike Medications

CPS PSO Health System Data
CPS’ PSO received reports on 30,609 incidents, near misses and unsafe conditions in 2018.

CPS PSO EMS Data
EMS continued to grow in 2018. There has been increasing interest in PSOs by larger organizations and also interest in collaborating to learn from the data submitted to the PSO. Organizations took advantage of the opportunity to submit data obtained from electronic event reporting systems.

The EMS Patient Safety Boot Camp had a very successful year providing participants with foundational principles of patient safety, including the importance of reporting events, near misses and unsafe conditions.

Currently EMS has over 2,000 events. The most frequently reported events to the EMS PSO database are relative to Behavioral Health patients, followed by Medications.

RESPIRATORY COMPROMISE

VIOLENCE AGAINST HEALTHCARE WORKERS

LOOK ALIKE SOUND ALIKE MEDICATIONS

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Full report will be released in the coming months.
REDUCING PREVENTABLE HARM.

The Center for Patient Safety, established in 2005, is an independent, not-for-profit organization dedicated to promoting safe and quality healthcare through the reduction of medical errors.