PATIENT SAFETY INITIATIVES TO REDUCE

SERIOUS MEDICAL ERRORS*

Since 2008, both Medicare and Medicaid have instituted patient safety initiatives to help reduce serious medical errors that occur in up to 1600 acute care hospitals (ACH) throughout the United States. Currently 26 of 50 States have followed their lead in requiring acute care hospitals to identify and report serious medical errors identified as "Never Events "(NE), "Adverse Events "(AE) and "Hospital Acquired Conditions "(HAC) not present on admission. They include certain infections identified as "Hospital Acquired Infections "(HAI). NE are also referred to as "Serious Reportable Events "(SRE) which are defined as clearly identifiable and measurable, preventable and serious in their consequences. The National Quality Forum (NQF) has identified 29 SRE which should never happen. NQF: Serious Reportable Events (qualityforum.org). Both Medicare and Medicaid as well as those States that require mandatory reporting of AE have incorporated most of these events. Since 2008 CMS Medicare and Medicaid have instituted regulations under the 2005 Deficit Reduction Act and HAC reduction program to deny or reduce payments to ACH for these adverse events and the increased medical costs associated with treatment for these events. https://www.cms.gov/newsroom/fact-sheets/eliminating-serious-preventable-and-costly-medical-errors-never-events. Private health insurers such as HMSA, a licensee for BCBS, have followed suit in denying payments for NE. https://hmsa.com/portal/provider/MM.12.007_Never_Events_and_Hospital_Acquired_Conditions.pdf

Some of the most egregious NE continue to include surgery on wrong body part, surgery on wrong patient, performing wrong surgical procedure, retained foreign object during surgery, medication errors, administration of incompatible blood products and intraoperative death during a low-risk surgery. The list has expanded to include HAC identified by CMS Medicare pursuant to the deficit reduction act to include the following events: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/Hospital-Acquired_Conditions

Foreign Object Retained After Surgery

Air Embolism

Blood Incompatibility

Stage III and IV Pressure Ulcers

Falls and Trauma

Fractures

Dislocations

Intracranial Injuries

Crushing Injuries

Burn

Other Injuries

Manifestations of Poor Glycemic Control

Diabetic Ketoacidosis

Nonketotic Hyperosmolar Coma

Hypoglycemic Coma

Secondary Diabetes with Ketoacidosis

Secondary Diabetes with Hyperosmolarity

Catheter-Associated Urinary Tract Infection (UTI)

Vascular Catheter-Associated Infection

Surgical Site Infection, Mediastinitis, Following Coronary Artery Bypass Graft (CABG):

Surgical Site Infection Following Bariatric Surgery for Obesity

Laparoscopic Gastric Bypass

Gastroenterostomy

Laparoscopic Gastric Restrictive Surgery

Surgical Site Infection Following Certain Orthopedic Procedures

Spine

Neck

Shoulder

Elbow

Surgical Site Infection Following Cardiac Implantable Electronic Device (CIED)

Deep Vein Thrombosis (DVT)/Pulmonary Embolism (PE) Following Certain Orthopedic Procedures:

Total Knee Replacement

Hip Replacement

Iatrogenic Pneumothorax with Venous Catheterization

Further, the HAI monitored and reported by CMS Medicare pursuant to the HAC reduction program include the following: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/HAC/Hospital-Acquired-Conditions

- Central Line-Associated Bloodstream Infection (CLABSI)
- Catheter-Associated Urinary Tract Infection (CAUTI)
- Surgical Site Infection (SSI) (for colon and abdominal hysterectomy procedures)
- Methicillin-resistant *Staphylococcus aureus* (MRSA) bacteremia
- *Clostridium difficile* Infection (CDI)

Pursuant to the HAC reduction program CMS Medicare and Medicaid will reduce annual reimbursement by 1% to ACH that have HAC and HAI rates that exceed the 75% percentile of the average hospital rate for the adverse event in question. This provides added financial incentives for hospitals to reduce HAC and NE. Medicare also provides hospitals with evidence-based guidelines to implement and help reduce these events. Medicare also rates hospitals for patient safety by measuring the incidence of 28 different HAC and NE and this

information is published and available to consumers to compare safety ratings of ACH.https://www.medicare.gov/care-compare/?providerType=Hospital&redirect=true#search.

The New York State Department of Health (NYSDOH) requires ACH to report adverse events which occurrences are tracked by the patient reporting and tracking system (NYPORTS). https://www.health.ny.gov/facilities/hospital/nyports/. The relevant statute, CPLR 2805-I and regulation 10 NYCRR 405.8 define the reportable adverse conditions which in substance are similar to Medicare's NE and HAC. The laws require that hospitals investigate and report AE to the NYSDOH within 30 days. The investigation must include a root cause analysis of the event and corrective plan of action in order to try to determine the reason for the event and help prevent future recurrences. However, all acquired information and the reports generated are to be kept confidential and are not discoverable in civil litigation. See CPLR 2805-M. The one exception is that statements made by a health care provider who is a party to a civil action regarding the event in question are discoverable. NYPORTS does publicly report a summary of statistics and analysis for ACH reports of AE for the time 2014-2017.https://www.health.ny.gov/facilities/hospital/nyports/annual_report/docs/2014-2017_statistical_report.pdf

The Leapfrog Group, a national not for profit patient safety organization, has for over 20 years promoted patient safety initiatives and reporting and accountability by hospitals for NE as defined by the NQF and CMS Medicare. See Leapfrog's fact summary for NE. https://ratings.leapfroggroup.org/sites/default/files/inline-files/2021%20Hospital%20Never%20Events%20Fact%20Sheet.pdf. The main goal of this organization is stated to be improve patient safety. Leapfrog reports over 250,000 patients die in hospitals each year due to preventable medical errors. One in 25 patients develop a preventable infection during hospitalization. One out of 4 have a chance for suffering an injury in the hospital. Leapfrog encourages hospitals to be transparent and report and account for preventable medical errors as measured by NQF and Medicare. Financial incentives through various purchasers are given to hospitals to help reduce NE. Since 2007 Leapfrog has implemented policies to require hospitals to timely report the event; give a verbal apology to patients and explanation of the known circumstances surrounding the

event; perform a root cause analysis of the event; waive medical costs for additional treatment for the complications caused by the event; and provide a plan for correction and prevention of the event. Leapfrog reports that patients are most angry if no one takes responsibility for the event. So, transparency and disclosure are of primary importance.

Leapfrog publicly reports hospital safety grades for nearly 3000 facilities using 30 evidenced based measures of patient safety established by NQF Medicare and other safety organizations currently adding post operative sepsis, blood leakage and kidney injury. The safety grades were recently updated in the fall 2021. Consumers have access to this website and can easily check and compare the safety rating of hospitals and statistics for occurrences of these serious medical errors. https://www.hospitalsafetygrade.org/. This is a very useful website and together with Medicare's website for "compare hospitals" can help consumers choose which hospitals have the best record for patient safety data. Leapfrog provides a letter grade rating system A, B, C, D and F with A being the best rating for patient safety and F the worst based on the hospital's reported occurrences and measures of NE. Only 32% of hospitals reporting received an A grade, 26% received a B, 35% a C, 7% a D and 1% an F. For example, in Long Island only Catholic Health St. Francis Hospital and NYU Langone Hospital/ Winthrop received Grade A while Stony Brook received a C and Good Samaritan Hospital and Nassau University Medical Center received a D. Unfortunately, too many hospitals do not timely and properly report serious medical errors and do not make timely disclosure to patients. Transparency is the exception rather than the rule.

Unfortunately, much more work needs to be done by hospitals to improve patient safety and reduce serious medical errors. The Agency for Healthcare Research and Quality (AHRQ) has published a scorecard for the incidence of hospital acquired conditions in acute care hospitals during 2014-2017, the most recent reportable period available. https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/quality-patient-safety/pfp/Updated-hacreportFInal2017data.pdf. Although there has been an overall reduction in hospital acquired conditions as defined by Medicare and NQF covering 28 measures of events (see report) during this time the numbers are staggering. In 2014 there were almost 3 million HAC or 99 per 1000 discharges. In

2017 there were still over 2.5 million HAC at a rate of 86 per 1000 discharges. It is estimated this 13% reduction saved 20,700 lives and 7.7 billion in medical costs. However, in 2017 still 8.6% of hospitalized patients had suffered a serious HAC. CMS and Medicaid continue to provide hospitals with the best evidence-based guidelines in order to help reduce harm. CMS's reported goal is to further overall reduce HAC by 20% by 2019. It is estimated that this will reduce HAC by 1.5 million patients, save 53,000 lives and 1.9 billion in hospital costs.

CONCLUSION

Additional Patient safety initiatives need to be implemented by hospitals and all healthcare providers and enforced by State health departments, Medicare, Medicaid and private health insurers to reduce and eliminate preventable medical errors known as never events. Hospitals need to be financially accountable by waiving extra medical costs for treatment of complications suffered from these events. Patient safety initiatives such as those instituted by Leapfrog requiring an apology and disclosure of serious medical errors to patients explaining the circumstances and cause (s) for the error and corrective plan of action need to be mandatory. Hospitals should be transparent in making full disclosure of medical errors to patients. State laws should compel hospitals to publish and make available to patients upon request reporting of all adverse events and hospital acquired conditions according to the parameters and measures set forth by the Agency for Healthcare Research and Quality, The National Quality Forum, and Medicare. The primary goal of all interested parties must be to enforce patient safety initiatives to eliminate all Never Events which will save millions of lives, prevent countless injuries and attendant economic losses and save billions of dollars in medical costs.

If you have experienced a serious injury at the hands of medical providers call our experienced team at Duffy & Duffy, PLLC 516-394-4200 for a free initial consultation with one of our attorneys or staff. We are dedicated to protecting your rights and holding wrongdoers accountable for injuries, harms and losses suffered by negligent or substandard medical care and treatment.

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