THE NEW FRONTIERS OF HEALTHCARE BATCH CLAIM LIABILITY

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June 2015
In the past, the principal risk exposure hospitals, healthcare systems, and healthcare organizations (“Healthcare Organizations”) faced was liability for negligent acts occurring in the provision of healthcare services. Healthcare Organizations managed that exposure, in part, by purchasing healthcare professional liability coverage to protect against allegations of negligence in the furnishing or failing to furnish “professional medical services.” But the days of successfully managing healthcare professional liability (“HPL”) risk by protecting only against single acts of claimed malpractice are over. The simple fact is that risk exposure from multiple events batched together is rising dramatically.

In the last decade, the healthcare industry has seen a significant rise in catastrophic claims (often called “super losses”) caused by poor outcomes or injuries from treatment by a provider or team of providers to a single patient. National studies have confirmed this trend. In the recent past, there have been seven HPL jury verdicts in excess of $50 million (resulting in aggregate loss exceeding $1 billion) in cases ranging from birth injuries to nursing home deaths.1

But even more concerning is the new reality of “related claim” exposure (also referred to as batch claims), which have increased in both size and frequency. Most related claim exposure so far has been from repeated negligent acts or other types of improper behavior by a single physician or professional staff employee that affected or injured multiple patients. (For example, the rogue employee committing criminal acts by poisoning patients; or the surgeon performing dozens of unneeded procedures for profit.) Because batch claim exposure has been linked to these types of unusual or esoteric fact patterns, Healthcare Organizations have tended to think of jumbo/related claim occurrences as 1 in 20 year “shock loss” events. This article suggests that thinking must change. Given the seismic changes under way in healthcare delivery and finance models - spurred by healthcare reform mandated under the Affordable Care Act - batch events are likely to occur with greater frequency in the new world of healthcare.

The purpose of this article is to explore and provide an overview of 1) the types of risks that have contributed to Healthcare Organization batch claims; 2) developments in the healthcare industry (market consolidation and healthcare reform) that will likely lead to more and bigger batch claims; and 3) the prospect that transformation of the healthcare industry will create a different breed of batch claim exposure based on allegations of financial misconduct and broad scale operational or system failure. This new class of claims will bear little resemblance to past cases involving poor or inadequate supervision of medical care. Finally, because batch event liability is the “new normal,” Healthcare Organizations will need to bolster risk management strategies to focus on these new exposures going forward.

RELATED EVENTS: TYPES OF BATCH CLAIMS AND LEGAL THEORIES USED TO SUPPORT THEM

Industry experience to date has shown that multiple patient exposure cases tend to be grouped in four broad categories:

- Medical necessity/unnecessary procedures (cardiac stents; chemotherapy; back surgery)²
- Sexual abuse/misconduct (molestation; privacy invasion)³
- Employee supervision (angel of death; drug addiction-related offenses)⁴
- Equipment Failure/Infections (improper sanitation and sterilization practices; “alarm fatigue”; food poisoning; malfunction of medication dispensing or radiation equipment)⁵

The common thread here is that these claims are closely connected with misfeasance in delivery of professional medical services. Resulting lawsuits are typically based on legal theories of direct corporate negligence by the Healthcare Organization or, alternatively, on vicarious liability theories. A direct corporate negligence claim is where the Healthcare Organization’s actions (or failures to act) caused patient harm. Under the corporate negligence approach, many courts have held hospitals directly accountable for negligent credentialing or re-credentialing of physicians – even of physicians who are not hospital employees.⁶ Under vicarious liability principles, hospitals have been responsible for negligent acts of employed physicians or professional staff (often referred to as respondeat superior or agency liability). Where a physician relationship with the hospital is solely as a medical staff member, vicarious liability of the hospital still exists for a physician’s medical negligence.⁷ This “apparent agency” liability occurs where a hospital holds out or represents to the public that the physician was “part of” the hospital.⁸

² “Judge Approves $37M Settlement in Stent Litigation”, Maryland Daily Record, May 23, 2014 (Settlement of two class action cases arising out of unnecessary cardiac stenting procedures); “Prosecutors Reach Overall Settlement of Allegations of Unneeded Cardiac Surgery”, 14 HLR 1487 (Nov. 17, 2005) (discussing U.S. and California ex rel Corapi and Zerga v. Tenet Healthcare Corp., No. CV-S-02-2423 (E.D. Cal.) alleging fraudulent billing for unnecessary cardiac procedures); “Dr. Atigo Durrani: New Trial Begins with West Chester Hospital, UC Health as Co-defendants”, WCPO TV (2013) (First of 285 lawsuits alleging unnecessary spine surgeries with hospital’s knowledge).
³ Tim Doe #1, et al. v. Saint Francis Hospital and Medical Center, et al., 309 Conn. 146 (2013) (Hospital liable for physician’s sexual molestation of hundreds of children under guise of phony “scientific” study); “Hospital Agrees to Pay $190 Million Over Recording of Pelvic Exams”, The New York Times, July 21, 2014 (Payment to over 7,000 women secretly recorded during pelvic exams by hospital gynecologist who used hidden camera concealed in a pen).
⁵ Cox System Settles 27 of 66 Radiation Lawsuits”, Springfield News Leader, February 18, 2012 (As many as 76 cancer patients exposed to 70% over-radiation due to human error in calibration, causing death in more than half of the patients); “Federal Judge Awards $1.25 in First Malpractice Trial Against VA Hospital Over Contaminated Endoscope”, LEXIS/NEXIS Legal Newsroom, December 12, 2012 (VA Hospital failed to properly sanitize medical equipment and infected patients with blood borne diseases including HIV, Hepatitis B, and Hepatitis C. More than 11,000 patients received colonoscopies over 5 years with improperly cleaned equipment).
⁶ Fletcher v. S. Peninsula Hosp., 71 p. 3d 833 (Alaska 2003) (Hospital negligently renewed surgeon’s staff privileges despite the fact that his reappointment application disclosed suspension of privileges at another facility, existing malpractice lawsuit, and termination of malpractice insurance coverage).
⁷ Boren ex rel. Boren v. Weeks, 251 S.W. 3d 436 (Tenn. 2008) (Hospital may be vicariously liable for negligent acts of independent physician where it can be shown that: (1) hospital held itself out to the public as providing medical services; (2) the patient looked to the hospital for performance of the medical services; and (3) the patient accepted those services under the reasonable belief that they were provided by the hospital rather than a particular individual physician).
⁸ Abdul-Majeed v. Emory Univ. Hosp. 455 S.E. 2d 270 (GA Ct. App. 1994) (Hospital may have direct liability to patient for independent physician’s negligence based solely on hospital nurse’s representation that patient would be treated by “one of our doctors”).
CASE STUDY: NEW ENGLAND COMPOUNDING CENTER

A highly publicized recent example of a medical negligence batch claim is the 2012 nationwide fungal meningitis outbreak linked to contaminated steroids produced by a Massachusetts-based pharmacy, New England Compounding Center (“NECC”). Thousands of people injected with the drug were affected. Of those injected, 751 people allegedly were diagnosed with meningitis, fungal infections and/or abscesses, and other injuries.9 Sixty-four of those 751 people allegedly died as a result of their infections.10 NECC was forced into bankruptcy, and reached a settlement valued at approximately $100 million (including $25.2 million from NECC insurers) to liquidate the civil liability of NECC and its owners.11

But that is not the end of the story. Healthcare organizations—including hospitals and other healthcare facilities face liability resulting from injections of patients with the contaminated drug for purposes of pain management and relief (primarily for spine conditions). The core of the liability theories stem from the alleged failure of such hospitals to conduct a site visit (as required by certain professional standard organizations) before ordering drugs from NECC, which purportedly would have revealed the rampant filth and lack of sterile conditions at NECC. Even for those patients who did not contract the disease, hospitals face damage claims for emotional distress and monitoring for future disease contraction. Legal theories against the hospitals include: (1) product liability as the “seller” of the contaminated compound, (2) vicarious liability for physicians failure to warn, and (3) civil conspiracy with NECC to avoid patient safety requirements in the bulk ordering process for steroids. The financial consequences stemming from one simple decision by hospitals to do business with a particular compounding pharmacy can have far reaching financial effects.12

9 Second Amended Master Complaint filed in the NECC Multidistrict Litigation (In re New England Compounding Pharmacy, Inc. Products Liability Litigation, MDL No. 2419, Docket No. 1:13-md-2419 (United States District Court, District of Massachusetts)) at ¶ 1.
10 Id. at § 3.
12 In fact, healthcare facilities and their insurers are contributing roughly $59.5 million to NECC’s bankruptcy estate. See Third Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. (In re New England Compounding Pharmacy, Inc., Case No. 12-19882 (United States Bankruptcy Court, District of Massachusetts, Eastern Division)) at §§ 1.86, 1.96, and 1.100. These contributions are being made in exchange for a channeling injunction that precludes any person or entity from making any claims against these healthcare facilities or their insurers in connection with the contaminated steroid produced at NECC. Additionally, other companies affiliated with NECC, including but not limited to the company that provided NECC with its clean-room, and the company that was responsible for testing the contaminated batches, are contributing to NECC’s bankruptcy estate. These contributions total roughly $47 million. Id. at §§ 1.20, 1.79, 1.114, 1.213, and 1.219. In total, the money collected by NECC’s bankruptcy estate stands at roughly $206.5 million.
REGULATORY FRAUD AND ABUSE – PRECURSOR TO BATCH BODILY INJURY CLAIMS UNDER HOSPITAL PROFESSIONAL LIABILITY POLICIES

We are also seeing an increase of bodily injury state law medical malpractice civil lawsuits alleging the performance of unnecessary surgical procedures in the wake of fraud and abuse regulatory enforcement actions. Creative plaintiff’s lawyers are waiting patiently in the wings for the government to announce its pursuit of health care providers for fraudulently billing Medicare and/or Medicaid for performance of medically unnecessary or experimental procedures before filing civil suits on behalf of hundreds of patients impacted by the healthcare providers’ alleged negligence. In addition to traditional state law medical malpractice causes of action, plaintiffs’ lawyers are now developing challenges to Healthcare Organization business practices based on business-related liability theories alleging fraud, misrepresentation, class action, unfair trade practice statutes, and even RICO.  

13“As Criminal Case Proceeds, [Law Firm] Pursues Medical Malpractice Action Against Dr. Aria Sabit on Behalf of Former Patient”, http://www.sommerspc.com/blog/2015/02. (Multiple civil lawsuits filed against spine surgeon and hospitals arising out of federal investigation for fraudulent billing for unnecessary back surgery on multiple patients). On May 22, 2015, a Birmingham neurosurgeon, Aria Sabit, 39, pleaded guilty to performing unnecessary spinal surgeries on patients and then unlawfully billing the government and private insurance companies $11 million for the operations.

MACRO TRENDS: INDUSTRY CONSOLIDATION AND HEALTHCARE REFORM

Hospital mergers and acquisitions are happening every day. Hospitals face shrinking reimbursements and the need for investment capital to acquire the latest technology. As Healthcare Organizations grow larger, more complex, and are more horizontally integrated along the continuum of care (outpatient – acute care – post-care recovery – residential life care), there is increased exposure to batch events related to system flaws or process failure.

But industry change is more fundamental and significant than just getting bigger. Healthcare reform has spurred a sea-change in healthcare delivery and payment models. The industry is moving away from fee-for-service. Reimbursement is now focusing on rewarding good outcomes and keeping people well. Healthcare Organizations receive bundled payments for episodes of care that include multiple services from different providers. Hospitals, payers and physicians are partnering to assume financial risk in healthcare delivery. Physicians and hospitals are becoming more clinically integrated than ever. To manage healthcare treatment services in a way that balances cost and quality, Healthcare Organizations rely increasingly on defined protocols (evidence-based medicine), big data (electronic medical records), and integrated delivery systems (coordinated care with shared financial risk). In some instances, traditional physician functions are being replaced by new technologies or by other licensed caregivers (“physician extenders”).

In this new paradigm, Healthcare Organizations are now more vulnerable to enterprise-wide liability exposure. As the size and breadth of Healthcare Organizations grows through consolidation, so too does the risk of adverse events caused by system flaws, or policy and procedure failures. We expect industry consolidation to increase frequency and severity of traditional, negligence-type batch claims alleging patient harm. But industry reimbursement reform will also lead to a new breed of “financial batch” claims.

“Furrow, “The Patient Injury Epidemic: Medical Malpractice as a Curative Tool,” Drexel Law Review, (Vol 4:41) (“Patients are killed or injured in hospitals because of system design shortcomings, failures of coordination…. This complexity - the combination of medical progress and industrialization – is producing more medical adverse events and errors...”)
NEW FRONTIER: FINANCIAL BATCH CLAIMS

Unlike batch claims focused on repeated instances of substandard care delivery, financial batch claims will focus on the business side of the healthcare industry. Integrated healthcare delivery systems that assume financial risk for bundled services or healthcare outcomes will face increasing pressure to remain financially profitable. Much like what managed care insurers experienced in the past, large constituencies of patients may claim that the type and quality of care they received from the Healthcare Organization was medically inappropriate, not because of medical negligence, but because of financial pressure to contain costs. Industry consolidation may also lead to a change in public perception about healthcare and the willingness to bring claims that a Healthcare Organization engaged in systematic incompetence or bad behavior. The local hospital may no longer be seen as a trusted community member but rather as part of a deep-pocketed healthcare conglomerate focused more on the bottom line than patient welfare. Even system failure claims such as infection control or equipment failure may be portrayed as rooted in the hospital’s inadequate system management or desire to control costs by skimping on operational controls.

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16 “Bigger Hospitals Mean Bigger Hospitals with Higher Prices. Not Better Care”. www.thehealthcareblog.com/2014/02/20 (“Power is shifting from physicians and other caregivers, whose duty (though they don’t always fulfill it) is to the needs of patients, towards administrators and corporations, whose loyalty lies with the institution or shareholders”).

17 “Health Care for Profit or People?”, Santa Clara University, www.scu.edu/ethics/publications (“The ethical implications of the growing commercialization of health care have become a matter of heated controversy. Those favoring the trend toward health care for profit claim that an increased role for entrepreneurs and competition in the delivery of health care will result in a more efficient and effective health care system. For others, the pursuit of profit is antithetical to the values central to medicine.”)

Hospital consolidation and an increasing focus on financial survival is changing the face of healthcare, which will result in new and more frequent exposure to enterprise-wide liability claims. Healthcare Organizations can no longer view this risk as a once in 20 year “shock loss” event. Reducing exposure to financial batch events will require risk management departments to expand oversight to virtually every area of hospital operations. Development of well thought out policies and procedures and effective monitoring of compliance with organizational policies and procedures will reduce the risk of batch exposure and limit the severity of such events when they do occur. Quality performance in healthcare will no longer be evaluated based just on the outcome of a specific medical procedure, but also virtually every other way in which a Healthcare Organization touches the lives of its patients.

“Traditional” HPL coverage – protecting a hospital against allegations by a patient of bodily injury caused by negligence – is not going away. In fact, this exposure is likely to continue to increase as more people become “users” of the healthcare system as a result of insurance coverage becoming more available under the ACA. And hospital risk managers will certainly have to continue their work to mitigate risk for these exposures especially as we see the rise in super losses. But, at the same time, batch claims are changing, and the frequency and potential severity of batch claims is increasing rapidly. One batch claim can eradicate an entire HPL tower of coverage, leaving virtually no limit for “traditional” HPL claims. Is that leveraged risk acceptable to a hospital risk manager or, more importantly, to a hospital’s CEO and/or CFO? Should hospital buyers be thinking about batch exposure the way property insurers think about property catastrophe exposure? Should these very different exposures be covered under the same liability insurance program? As batch claims increase in frequency and visibility, their impact on both traditional (healthcare) risk management and financial risk management will also grow.
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06/15