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Hospital Acquired Infections Reporting Requirements and False Claims Act Liability: Improving Reporting Standards to Better Serve All Parties

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Abstract

Hospital-acquired infections are infections sustained as a result of hospitalization. Nationwide, these account for many injuries and deaths each year. In an attempt to lower hospital-acquired infection (HAI) rates, the federal government has implemented a system of rewards and penalties for participating hospitals who report hospital-acquired infection rates. This system involves ranking hospitals according to reported HAI rates, and tracks improvement in rates each year. Using both rank and improvement data, the Centers for Medicare and Medicaid Services (CMS) simultaneously rewards hospitals under its Value-Based Purchasing Program, and penalizes hospitals under its Hospital Acquired Conditions Reduction Program. Hospitals ranking in higher quartiles and hospitals demonstrating improved HAI rates (i.e., lower HAI rates) can receive bonuses. Ironically, many prominent academic medical centers have been on the receiving end of penalties because they fall in the bottom quartile rank for HAI rates.

With the current system of rewards and penalties, some hospitals may be tempted to underreport infection rates. This puts hospitals at risk for False Claims Act liability. The following article looks at tracking hospital acquired infection (hereafter "HAI") rates to improve hospital quality and safety. It examines the current system of rewards and penalties for reported HAIs. It looks at the perception of federal agencies such as the Office of Inspector General, the CMS, and the Centers for Disease Control on the validity of reported HAI rates. It then describes the False Claims Act, focusing on implied certification and materiality, using applicable case law as context, including the seminal FCA case, *Escobar*. Finally, it urges a serious consideration of connecting Conditions of Participation to compliance with HAI reporting requirements.

INTRODUCTION

In 2014, under the Hospital-Acquired Conditions Reduction Program (HACRP), the Centers for Medicare and Medicaid Services (CMS) penalized nine Chicago hospitals for ranking among the lowest quartile of hospitals in the nation in terms of hospital-acquired conditions, including hospital-acquired infections.[1] According to Kaiser Health News, the worst ranking Chicago hospital that year was Northwestern Memorial Hospital,[2] which lost $1.5 million in Medicare reimbursements in 2015, based in part on reported hospital-acquired infection rates.[3] This represented a reduction of 1% in the hospital's Medicare payments that year.[4] According to Kaiser Health News, Grady Memorial Hospital, an academic medical center in Atlanta, lost

[1] Ellen Hirst et al., *Infection Rate Penalties Hit Chicago-area Hospitals*, CHI. TRIB., (December 20, 2014), http://www.chicagotribune.com/business/ct-hospital-infection-rates-1220-biz-20141219-story.html

[2] Jordan Rau, *721 Hospitals Penalized for Patient Safety*, KHN, (2014), https://khn.org/news/721-hospitals-penalized-for-patient-safety/

[3] Hirst, *supra* note 1.

[4] Rau, *supra* note 2.

reimbursements in 2016.[5] In 2017, the Cleveland Clinic lost reimbursements.[6] In 2018, the University of Virginia Medical Center lost reimbursements.[7] That same year, Yale New Haven Hospital would be penalized for the fourth year in a row since the CMS had implemented penalties for the lowest performing hospitals.[8] Because of the financial risk associated with penalties for what is deemed poor performance, some hospitals may be tempted to underreport infection rates, to avoid being in the lowest quartile of all reporting hospitals (which are subject to 1% reduction in Medicare reimbursement rates).[9] This is known as gaming the system.[10]

In some instances, the federal government relies upon infection rate data collected by states. Among states that mandate reporting HAIs are states which specifically exempt critical access hospitals from reporting.[11] Critical access hospitals are hospitals in rural areas that have 25 or less inpatient beds.[12] One reason for exempting critical access hospitals is based on the numbers required to accurately predict what an infection rate should be for a given hospital, using Standardized Infection Ratios (SIRs).[13] These numbers refer to either number of infections or number of device days, i.e., number of days a specific device is in place that could cause infection, such as a urinary catheter or a central line.[14] Many critical access hospitals have such low numbers of infection that an increase of even one infection per year could cause them to fall into the bottom quartile. One result of excluding critical access hospitals from reporting is that the remaining hospitals in the lower end of the third quartile could fall into the fourth quartile, subjecting them to penalties that might otherwise be assessed against critical access hospitals.

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[5] Jordan Rau, *758 Hospitals Penalized for Patient Safety in 2016: Data Table*, KHN, (2015), https://khn.org/news/758-hospitals-penalized-for-patient-safety-in-2016-data-table/

[6] Jordan Rau, *769 Hospitals Penalized for Patient Safety in 2017: Data Table*, KHN, (2016)., https://khn.org/news/769-hospitals-penalized-for-patient-safety-in-2017-data-table/

[7] Jordan Rau, *758 Hospitals Penalized for Patient Safety in 2018: Data Table*, KHN, (2017), https://khn.org/news/751-hospitals-hit-with-safety-penalties-for-2018-data-table/

[8] Isabel Bysiewicz, *Yale New Haven Hospital Sees Medicare Payments Cut for Fourth Straight Year* (2018), https://yaledailynews.com/blog/2018/01/06/yale-new-haven-hospital-sees-medicare-payments-cut-for-fourth-straight-year/ (The common thread connecting Northwestern, Grady, Cleveland Clinic, University of Virginia, and Yale University Hospital is that they are all premier academic medical centers.)

[9] The Centers for Medicare and Medicaid Services, *Hospital-Acquired Condition Reduction Program* (2017), https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/HAC-Reduction-Program.html

[10] Daniel Levinson, *CMS Validated Hospital Inpatient Quality Data, But Should Use Additional Tools to Identify Gaming*, 16, (2017), https://oig.hhs.gov/oei/reports/oei-01-15-00320.pdf

[11] Michelle Casey et al., *Reporting of Healthcare-Associated Infections by Critical Access Hospitals,* 3 (2015), http://www.flexmonitoring.org/wp-content/uploads/2015/09/HAI-Reporting.pdf

[12] 42 U.S. Code §1395i-4(2)(B)

[13] The Centers for Disease Control and Prevention, *The NHN Standardized Infection Ratio*, (2018), https://www.cdc.gov/nhsn/pdfs/ps-analysis-resources/nhsn-sir-guide.pdf

[14] *Id.*

While the HACRP subjects low-ranking hospitals to penalties, the CMS's Value-Based Purchasing Program awards bonuses to hospitals for performing well in four domains of quality.[15] One of the domains includes safety measures, including rates of various HAIs. Bonuses are awarded for the greater of two scores: achievement or improvement.[16] However, many bonuses are never realized, because they are offset by penalties assessed by other federal programs, including HACRP.[17]

Gaming the system for infection reporting not only calls into question the reliability of reported data to evaluate the efficacy of infection prevention measures but also exposes hospitals to liability for false claims. The goal of this article is to show how systematically underreporting infection rates in order to earn bonuses and avoid penalties can violate the False Claims Act. In addition, it will make the case for changing health care policy to improve the integrity of infection rate reporting and increasing support for those facilities that need help with infection prevention.

In order to examine the current system of rewards and penalties for reported infection rates, this article will begin with a discussion of hospital-acquired infection tracking to improve quality and safety, including which hospitals are required to report infection rates. Second, it will cover how a lack of consistency in reporting within states can affect the reliability of reported data, what factors affect the accuracy of reporting, and how varying methods of data analysis result in different pictures of a hospital's performance. Third, it will consider two federal programs that may encourage gaming: Value-based Purchasing, and Hospital-Acquired Infections Reduction Program. Fourth, it will discuss the OIG recommendations to the CMS and the CDC to improve validation methods. Fifth, it will consider the False Claims Act in general, with exploration of *qui tam* litigation. Next, it will examine various False Claims Act cases that illustrate the components of a false claim, highlighted by discussion of *Escobar*, the seminal case covering implied certification as a theory of false claims liability. Finally, it will offer a prescription for improving HAI reporting practices and avoiding false claims liability.

I. TRACKING HOSPITAL-ACQUIRED INFECTIONS TO IMPROVE QUALITY AND SAFETY

A hospital-acquired infection,[18] also known as a healthcare associated infection[19] or a healthcare-acquired infection (HAI),[20] is an infection that occurs as a result of hospitalization. Types of HAI include CLABSI (central line associated bloodstream infection), CAUTI (catheter acquired urinary tract infection), SSI (surgical site infection), and Clostridium difficile (C-diff.)[21] The Agency for

[15] The Centers for Medicare and Medicaid Services, *Hospital Value-Based Purchasing*, 1, 2 (2017), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Hospital_VBPurchasing_Fact_Sheet_ICN907664.pdf

[16] *Id*. at 6.

[17] Jordan Rau, *1,700 Hospitals Win Quality Bonuses From Medicare, But Most Will Never Collect*, (2015), https://khn.org/news/1700-hospitals-win-quality-bonuses-from-medicare-but-most-will-never-collect/

[18] Haldee Custodio, *Hospital-Acquired Infections* (2016) https://emedicine.medscape.com/article/967022-overview

[19] The Centers for Disease Control and Prevention, *HAI Data and Statistics*, (2016), https://www.cdc.gov/hai/surveillance/

[20] The Centers for Medicare and Medicaid Services, *Hospital-Acquired Conditions Reduction Program*, (2015), https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/HAC/Hospital-Acquired-Conditions.html

[21] The Agency for Healthcare Research and Quality, *Health Care-Associated Infections* (2017), https://psnet.ahrq.gov/primers/primer/7/health-care-associated-infections

Healthcare Research and Quality estimates that 650,000 patients contract an HAI annually.[22] According to the Institute for Healthcare Improvement, an HAI can cause death in some individuals.[23] The Institute of Medicine reported that hospital-acquired infections resulted in 100,000 deaths in 2002.[24] In 2014, hospital-acquired infections resulted in 75,000 deaths.[25] In addition, it is estimated that HAIs result in an additional $45 billion annually in direct hospital costs.[26]

The Agency for Healthcare Research and Quality is a federal agency whose primary purpose is to improve quality and safety in America's healthcare.[27] One of its areas of focus is to develop training materials for system-wide use, including the Comprehensive Unit-Based Safety Program (CUSP), which is used to help prevent hospital acquired infections.[28] The CUSP originated with Dr. Peter Pronovost of Johns Hopkins Hospital.[29] It has been implemented in over 1,100 adult intensive care units nationwide, and is credited with reducing the central line-associated bloodstream infection rate by forty percent.[30]

Since 2007, the CMS has required participating hospitals to assign a present on admission ("POA") indicator to primary and secondary diagnoses for inpatient prospective payment system acute care claims for hospital discharges.[31] In an effort to decrease HAI rates, since 2008, the CMS has put limits on reimbursement for conditions it deems preventable.[32] These include the HAIs listed above.[33] A recent study suggests that the CMS's failure to reimburse for HAIs causes some hospitals to upcode reporting, claiming infections are present on admission, and not hospital-acquired.[34] The study found that hospitals in states with weaker mandatory reporting requirements

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[22] *Id.*

[23] The Institute for Healthcare Improvement, *What Zero Looks Like: Eliminating Hospital-Acquired Infections*. (Last accessed 11/10/17), http://www.ihi.org/resources/Pages/ImprovementStories/WhatZeroLooksLikeEliminatingHospitalAcquiredInfections.aspx

[24] Samuel Peasah et al., *Medicare Non-payment of Hospital-Acquired Infections: Infection Rates Three Years Post Implementation,* 3 MMRR E1, E1 (2013), https://www.cms.gov/mmrr/Downloads/MMRR2013_003_03_a08.pdf

[25] The Centers for Disease Control and Prevention, *HAI Data and Statistics*, (2018), https://www.cdc.gov/hai/surveillance/

[26] Edward Kennedy et al., *Estimating Hospital Costs of Catheter-Associated Urinary Tract Infection* (2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3786530/

[27] The Agency for Healthcare Research and Quality, *Agency for Healthcare Safety and Quality: A Profile* (2017), https://www.ahrq.gov/cpi/about/profile/index.html

[28] The Agency for Healthcare Research and Quality, *What Are AHRQ's Areas of Focus?* (2017), https://www.ahrq.gov/cpi/about/profile/index.html

[29] Peter Pronovost et al., *Implementing and Validating a Comprehensive Unit-Based Safety Program* (2005), http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.462.9196&rep=rep1&type=pdf

[30] The Agency for Healthcare Research and Quality, *Stories of Success: Using CUSP to Improve Safety* (2012), https://www.ahrq.gov/professionals/quality-patient-safety/cusp/cusp-success/whatiscusp.html

[31] Office of Inspector General, *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries*, (2010), https://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf

[32] Peter Pronovost et al., The *Wisdom and Justice of Not Paying for "Preventable Complications*," (2008), https://psnet.ahrq.gov/resources/resource/7284

[33] Arnie Mackles and Tom Syzek, *Healthcare-Associated Infections* (last accessed 1/27/18) http://blog.thesullivangroup.com/healthcare-associated-infections

[34] Edmund Andrews, *How Hospitals Avoid Penalties for Making Patients Sick* (2016) http://www.newswise.com/articles/how-hospitals-avoid-penalties-for-making-patients-sick

were reporting fewer HAIs than states with strong regulations, and higher rates of infection present on admission.[35] The study estimated that inaccurate infection reporting resulted in inappropriate reimbursement of $200 million for approximately 11,000 cases of upcoded infections.[36] Ironically, the study suggests that hospitals that report more hospital-acquired infections might have higher standards of care.[37] As will be shown later, when facilities engage in systematic upcoding of infections, representing them as present on admission (POA) and not as HAI, they risk false claims liability.

The majority of states require hospitals to report HAI rates monthly[38] to the National Healthcare Safety Network (NHSN), a surveillance system[39] of the Centers for Disease Control and Prevention (CDC) that is considered the most widely used HAI tracking system in America.[40] Reporting hospitals use a monthly checklist to track the following HAIs: CAUTI, CLABSI, C-diff, SSI, and methicillin resistant staphylococcus aureus (MRSA).[41] The CDC uses this database to report infection rates to the CMS for each reporting hospital.[42]

To better track HAI rates, the CDC has attempted to standardize reporting requirements to determine whether an infection is considered present on admission (POA) or hospital-acquired.[43] There are several factors for determining whether an infection is present on admission, the most important of which is the 7 day infection window period (IWP).[44] This period uses either the date of the first diagnostic test that reveals an infection, or the first appearance of a localized sign of infection as a marker, and adds three days before this date and three days after this date to determine the IWP.[45] Other factors include the: date of an event, which is the date of the first

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[35] Hamsa Bastani et al., *Evidence of Upcoding in Pay for Performance Programs,* 1, 34 (2017), https://web.stanford.edu/~bayati/papers/upcoding.pdf

[36] *Id.* at 35.

[37] Edmund Andrews, *How Hospitals Avoid Penalties for Making Patients Sick* (2016) http://www.newswise.com/articles/how-hospitals-avoid-penalties-for-making-patients-sick

[38] The Centers for Disease Control and Prevention, *Operational Guidance for Acute Care Hospitals to Report Central-Line Associated Bloodstream Infection (CLABSI) Data to CDC's NHSN for the Purpose of Fulfilling CMS's Hospital Inpatient Quality Reporting Requirements* (2014). https://www.cdc.gov/nhsn/pdfs/cms/Final-ACH-CLABSI-Guidance-2015.pdf

[39] The Centers for Disease Control and Prevention, *National Healthcare Safety Network* (last viewed 2/17/2018), https://nhsn.cdc.gov/RegistrationForm/index

[40] The Centers for Disease Control, *State-based HAI Prevention* (2016), https://www.cdc.gov/nhsn/about-nhsn/index.html

[41] *NHSN Monthly Checklist for Reporting to CMS IQR*, 1, (2015). https://www.cdc.gov/nhsn/pdfs/cms/ach-monthly-checklist-cms-iqr.pdf

[42] Levinson, *supra* note 17, at 2.

[43] The Centers for Disease Control, *Identifying Healthcare-Associated Infections (HAI) for NHSN Surveillance,* 2-3 (2018) https://www.cdc.gov/nhsn/pdfs/pscmanual/2psc_identifyinghais_nhsncurrent.pdf

[44] *Id.* at 2-3.

[45] *Id*.

element signaling an infection within the IWU;[46] the timeframe to be considered for stating that an infection is present on admission, which is from two days before to one day after the admission date;[47] the timeframe for a hospital acquired infection, which is on or after the second day after the admission date;[48] the 14-day repeat infection timeframe (RIT), which is the two week timeframe during which no new infections are identified, with day one of the two weeks being the date of infection;[49] secondary bloodstream infection attribution period (SBAP), which is the time frame of a secondary bloodstream to be attributable to a primary site infection (i.e., MRSA as blood stream infection attributable to MRSA of a wound);[50] pathogen assignment guidance, which connects secondary pathogens sustained during with original site infections (i.e., secondary infections sustained during RIT or SBAP);[51] and location of attribution, which is where the patient was assigned as an inpatient when an infection occurred.[52]

The CDC has published operational guidelines for reporting hospital acquired infections.[53] For example, one category of reportable infection is central-line associated bloodstream infection (CLABSI).[54] The process for reporting a CLABSI involves using NHSN's Bloodstream Infection ("BSI") Form.[55] This form includes details such as demographic information, date of event, signs and symptoms of infection, and physician diagnosis.[56]

A. CDC and CMS Acknowledge Anecdotal Evidence of Underreporting

There is a paucity of evidence concerning gaming the system. However, the CDC and the CMS issued a report to healthcare facilities about intentional underreporting of hospital acquired infection rates, in response to anecdotal evidence of intentional underreporting.[57] The report details several ways underreporting can occur, and warns those who might report incorrect data or fail to report according to NHSN requirements that they might be subject to civil monetary penalties and exclusion from Medicare participation.[58] The Office of Inspector General (OIG) referenced this

[46] *Id*. at 2-7.
[47] *Id*.
[48] *Id*.
[49] *Id*. at 2-9.
[50] *Id*. at 2-13.
[51] *Id*. at 2-17.
[52] *Id*. at 2-24.

[53] Operational Guidance for Acute Care Hospitals. (Last accessed 1/13/2018). https://www.cdc.gov/nhsn/cms/
[54] Operational Guidance for Acute Care Hospitals to Report Central Line-Associated Bloodstream Infection (CLABSI) Data to CDC's NHSN for the Purpose of Fulfilling CMS's Hospital Inpatient Quality Reporting (IQR) Requirements (2014). https://www.cdc.gov/nhsn/pdfs/cms/Final-ACH-CLABSI-Guidance-2015.pdf

[55] National Healthcare Safety Network, *Primary Bloodstream Infection Form* (last accessed 3/26/18). https://www.cdc.gov/nhsn/forms/57.108_PrimaryBSI_BLANK.pdf
[56] *National Healthcare Safety Network Custom Event form* (last accessed April 14, 2018), https://www.cdc.gov/nhsn/forms/57.115_CUS_BLANK.pdf
[57] National Healthcare Safety Network, *Adherence to the Centers for Disease Control and Prevention's (CDC's) Definitions and Criteria is Needed to Ensure Accuracy, Completeness, and Comparability of Infection Information* (2015) https://www.cdc.gov/nhsn/cms/cms-reporting.html
[58] *Id.*

report in its analysis of the CMS's validation of inpatient quality data, recommending that the CMS use analytics to identify whether gaming was occurring at healthcare facilities.[59]

II. LACK OF CONSISTENCY, ACCURACY, AND RELIABILITY CAN AFFECT INTEGRITY OF REPORTED DATA

A. Lack of consistency affects integrity of reported data

Some states have externally validated what hospitals have reported to NHSN, including California,[60] Connecticut,[61] and Oregon.[62] The California Department of Public Health used claims-based surveillance to identify surgical site infections (SSIs) in a study population consisting of 42 hospitals, comparing it to traditional surveillance in those hospitals.[63] Results showed that claims-based surveillance had a higher sensitivity than traditional surveillance, revealing 119 unreported cases among the 42 hospitals.[64]

In Connecticut, a validation study of 30 acute care hospitals looked at medical records from the fourth quarter of 2008 for instances of CLABSI.[65] Among the 476 instances of bloodstream infections (known as septic infections, or sepsis), 48 instances were CLABSI.[66] The hospital failed to report 25 of these to the NHSN.[67] The study attributed some underreporting to misinterpretation of the criteria for CLABSI; however, the study found no apparent reason for underreporting other reportable instances of CLABSI.[68]

In Oregon, the Oregon Public Health Division (OPHD) used medical record review to validate reported incidences of CLABSI in 44 Oregon hospitals.[69] This study found discrepancies between hospital reporting rates and OPHD identification of CLABSI, with six percent of episodes of

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[59] Levinson, *supra* note 17, at 14.

[60] Michael Caldenwood et al., *Use of Claims Data to Identify Cases of Surgical Site Infection Following Colon Surgery Identified Many Unreported Infections in a State-Wide Validation* (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5781759/

[61] Lauren Backman et al., *Validation of the Surveillance and Reporting of Central Line-Associated Bloodstream Infection Data to a State Health Department*, (2010), https://pdfs.semanticscholar.org/ae7a/022740693394cf7d7adbff9f876d1b9021ed.pdf

[62] John Oh et al., *Statewide Validation of Hospital-Reported Central Line-Associated Bloodstream Infections: Oregon, 2009* (2012), http://www.oregon.gov/oha/PH/DISEASESCONDITIONS/COMMUNICABLEDISEASE/HAI/Documents/clabsi-oh-article.pdf

[63] Caldenwood, *supra* note 54.

[64] *Id.*

[65] Backman *supra* note 61 at 833

[66] *Id*. at 834.

[67] *Id.*

[68] *Id*. at 835, 837.

[69] John Oh et al., *Statewide Validation of Hospital-Reported Central Line-Associated Bloodstream Infections: Oregon, 2009*, *SHEA*, 439 (2012), http://www.oregon.gov/oha/PH/DISEASESCONDITIONS/COMMUNICABLEDISEASE/HAI/Documents/clabsi-oh-article.pdf

failure to report attributed to misclassifying CLABSI as present on admission.[70] The study authors recommended that those completing external validation discuss differing findings with the hospitals being studied, in order to increase the accuracy of identifying a CLABSI.[71]

Other states that do not have mandatory reporting requirements, such as Arizona[72] and Montana,[73] still use the NHSN data to identify trends in HAIs. Arizona's Department of Health Services has an extensive HAI surveillance program, including a data use agreement between the CDC and its department.[74] Arizona acknowledges the need for surveillance, but prioritizes infection prevention measures over infection reporting.[75] Montana's Department of Public Health and Human Services describes a data use agreement between the CDC and its department.[76] They acknowledge that hospitals end up reporting data to the NHSN anyway, because that enables them to participate in programs such as value-based purchasing, which require HAI reporting.[77] According to Montana Department of Health and Human Services, keeping reporting voluntary has enabled Montana to more easily respond to changes in federal law.[78]

A recent qualitative study from the *British Medical Journal of Quality and Safety* examined trends in state laws concerning HAI reporting.[79] The study highlighted the need for external validation of hospital-reported data, as well as timeliness of publicly reported data.[80] Interestingly, state-specific data was considered more timely than federal data, with the perception that the federal data was less relevant, since it was 18 to 24 months old.[81]

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[70] *Id*. at 442.

[71] *Id*. at 444.

[72] Geoff Granseth, *Evaluation of National Healthcare Safety Network (NHSN) Data Available Through the Arizona Department of Health Services Data Use Agreement (DUA)*, (last accessed 3/7/2018), http://azdhs.gov/documents/preparedness/epidemiology-disease-control/healthcare-associated-infection/nhsn-evaluation-report.pdf

[73] Arizona Department of Health Services, *Frequently Asked Questions About DPHHS and the CDC/NHSN Data Use Agreement* (2015), https://dphhs.mt.gov/Portals/85/publichealth/documents/CDEpi/DiseasesAtoZ/HAI/What%20is%20NHSN%20and%20the%20MT%20DUA%20FAQ.pdf

[74] Granseth, *supra* note 66, at 3.

[75] Arizona Department of Health Services, *Surveillance Subcommittee's "Bottom Line" Presentation*, (last accessed 3/14/18). http://www.azdhs.gov/documents/preparedness/epidemiology-disease-control/healthcare-associated-infection/advisory-committee/surveillance/healthcare-associated-infections-the-bottom-line.pptx

[76] Montana Department of Public Health & Human Services, *Frequently Asked Questions About DPHHS and the CDC/NHSN Data Use Agreement,* 1, 1 (2015), https://dphhs.mt.gov/Portals/85/publichealth/documents/CDEpi/DiseasesAtoZ/HAI/What%20is%20NHSN%20and%20the%20MT%20DUA%20FAQ.pdf

[77] *Id.* at 2.

[78] *Id*.

[79] Patricia Stone et al., *Impact of Laws Aimed at Healthcare-Associated Infection Reduction: A Qualitative Study*, BMJ Qual Saf., 637 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4575878/

[80] *Id.* at 641.

[81] *Id.*

B. Accuracy of infection reporting affects integrity of reported data

One factor that affects reportable infection rates is increasingly better technology.[82] Improved technology allows for greater sensitivity and precision, but also increases the likelihood of increasing the number of reportable HAIs.[83] For example, a positive blood culture previously identified as a contaminant because of less precise technology may now be identified as a reportable CLABSI, because a more sensitive test is used.[84] Another example is using a more sensitive test to detect clostridium difficile infection (CDI).[85] Nucleic acid amplification tests have a higher sensitivity than enzyme immunoassays (EIAs).[86]

Using nucleic amplification tests may result in higher reportable infection rates of CDI.[87] Rather than celebrate the ability to better detect HAIs, hospital administrators worried about the bottom line may try to pressure infection preventionists to go back to the less sensitive tests, in order to lower rates of reportable infections.[88] Systematic pressure to change testing in order to lower reportable infection rates, in order to decrease penalties and maximize bonuses would put a facility at risk of false claims liability.

Further, even those intending to accurately report infection rates can underreport due to the subjective nature of infection determination.[89] For instance, some infection reporters may require a high probability of certainty before reporting an infection as an infection.[90] This is known as favoring specificity over sensitivity.[91] Specificity refers to the high likelihood of a patient having an infection if a test for that infection is positive.[92] A highly specific test will pick up most patients with true infections, but may miss other patients who are also infected.[93] By contrast, sensitivity refers to the high likelihood of a patient not having an infection if a test for that infection is negative.[94] A highly sensitive test picks up most patients with an infection, but may also pick up patients without an infection, adversely affecting reportable infection rates.[95] Just before the CMS

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[82] Daniel Diekema, *Rising Stakes for Health Care-Associated Infection Prevention: Implications for the Clinical Microbiology Laboratory*, J. Clin. Microbiol., 996 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5377856/

[83] *Id.*
[84] *Id.*
[85] *Id.*
[86] *Id.*
[87] *Id.*
[88] *Id.*
[89] William Trick, *Decision Making During Healthcare-Associated Infection Surveillance: A Rationale for Automation,* 57 Clin Infect Dis, 3, at 434 (2013), https://academic.oup.com/cid/article/57/3/434/461013

[90] *Id.*
[91] *Id.*

[92] Thomas Tape, *Interpreting Diagnostic Tests* (last accessed March 18, 2018). http://gim.unmc.edu/dxtests/Default.htm
[93] Gavi Kohlberg, *Explanation of Sensitivity and Specificity and How to Use Them*, (2008), http://getthediagnosis.org/definitions.html
[94] Tape, supra note 86
[95] Kohlberg, *supra* note 87

initiative to no longer pay for preventable errors such as HAIs was implemented, clinicians discussed the complex nature of connecting the concepts of HAI and preventable harm.[96] They felt that low prevalence of some HAIs, along with imperfect sensitivity and specificity determinations would introduce bias into the measurement.[97]

C. *Varying methods of data analysis affect the integrity of reported data*

There is also a lack of standardization in data interpretation, leading to misleading results when HAI rates are reported to the NHSN.[98] This is attributed to the different methods of identifying an HAI as an HAI.[99] While some institutions use fully automated electronic surveillance, others use semi-automated electronic surveillance.[100] This latter method allows varying degrees of manual input by an individual, such as an infection preventionist.[101] In fact, HAI rates are no longer the measure used in NHSN data analysis.[102] Instead, NHSN uses the standardized infection ratio (SIR), which compares the observed occurrence of HAIs to the predicted occurrence of HAIs, in order to overcome differences in risk among patient populations, and enable comparison across facilities.[103] However, as long as institutions are reporting HAIs, there will be variability depending on an institution's method of reporting data to the NHSN. A possible solution to lessen inconsistency in data interpretation would be to move from manual surveillance to at least semi-automated, and ideally, fully automated surveillance.[104]

Adding to the challenge of inconsistent methods of data reporting, there are discrepancies between what hospitals report to the CMS and what their patient safety scores, termed patient safety indicators (PSIs), are.[105] The Agency for Healthcare Research and Quality created PSIs to give a picture of a hospital's quality compared to other hospitals.[106] When other entities create PSIs, they may leave out important data that would affect PSI rates. An example of this occurred with U.S. News and World Report's (USNWR) determination of PSI rates, based on a limited data set known as MedPAR.[107] Rather than relying on data that had been directly reported to the CMS, USNWR

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[96] Peter Pronovost et al., *The Wisdom and Justice of Not Paying for "Preventable Complications,"* JAMA, 2197 (2008), http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.462.9196&rep=rep1&type=pdf

[97] *Id.*

[98] David Shahian et al., *The Quality Measurement Crisis: An Urgent Need for Methodological Standards and Transparency*, 42 Joint Commission Journal on Quality and Patient Safety, 435 (2016), http://www.jointcommissionjournal.com/article/S1553-7250(16)42057-X/pdf

[99] Keith Woeltje et al., *Data Requirements for Electronic Surveillance of Healthcare-Associated Infections*, 35 Infect Control Hosp Epidemiol 9 at 1383, 1383 (2014), http://www.jstor.org/stable/10.1086/677623

[100] *Id.*

[101] *Id.*

[102] The Centers for Disease Control and Prevention, *The NHSN Standardized Infection Ratio*, 1, 4 (2017), https://www.cdc.gov/nhsn/pdfs/ps-analysis-resources/nhsn-sir-guide.pdf

[103] *Id.*

[104] Woeltje, *supra* note 93, at 1383

[105] *Id.*

[106] The Department of Health and Human Services, *AHRQ Quality Indicators, Guide to Patient Safety Indicators*, 1, 1 (2007), http://www.qualityindicators.ahrq.gov/downloads/modules/psi/v31/psi_guide_v31.pdf

[107] Shahian, *supra* note 92, at 435.

used MedPAR, which leaves out certain data elements to prevent identification of CMS beneficiaries.[108] These included missing procedure dates and present on admission (POA) indicators, resulting in falsely increased PSI rates, making some hospitals appear worse than they actually are.[109] When a hospital's reputation can be affected by reported PSIs, and consumers choose hospitals based on safety information, a hospital may be tempted to game the system to put themselves in a better light to the public.

III. FEDERAL POLICIES MAY RESULT IN GAMING

Since 2012, the federal government has offered financial incentives to hospitals to decrease hospital-acquired infection rates.[110] The CMS incentivizes a hospital's quality performance with value-based purchasing.[111] Value-based purchasing is a CMS program that began making incentive payments in 2012[112] to participating hospitals based on quality scores across several domains, one of which is safety.[113] Within the safety domain are measurements of HAI occurrences.[114] Though what is measured depends on the specific fiscal year (for example, the catheter-associated urinary tract infection rate was tracked in 2016 and the clostridium difficile infection rate was measured in 2017)[115] the value-based purchasing program consistently considers a hospital's HAI rate when determining whether to award bonus payments.[116]

Taking a lesson from the Atlanta teacher cheating scandal, in which teachers changed the bubbled-in answers on standardized tests in order to make sure their failing school was not closed down due to poor test performance,[117] one hospital epidemiologist has opined that pay for performance measures could cause clinicians to possibly harm patients in order to report "appropriate" infection rates.[118] An example of this would be doing a urine culture instead of a blood culture when a patient had bacteremia, and pulling out that patient's central line rather than determining that the bacteremia was due to an infected central line, requiring the reporting of a CLABSI to NHSN.[119] Another example is using antibiotics on catheterized patients if urine tests showed inflammatory

[108] *Id.*
[109] *Id*. at 436.
[110] The Centers for Medicare and Medicaid Services, *Hospital-Acquired Condition Reduction Program*, (2017). (Last accessed 11/8/2017), https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/HAC-Reduction-Program.html
[111] The Centers for Medicare and Medicaid Services, *Frequently Asked Questions Hospital Value-Based Purchasing Program,* 1, 3 (2012), (Last accessed 11/11/17). https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/downloads/HVBPFAQ022812.pdf
[112] *Id.*
[113] The Centers for Medicare and Medicaid Services, *supra*, note 110, at 1.
[114] *Id.*
[115] *Id.* at 3.
[116] *Id.*

[117] Rachel Aviv, *Wrong Answer* (2014). https://www.newyorker.com/magazine/2014/07/21/wrong-answer
[118] Mike Edmond, *Wrong Answer* (2017) http://haicontroversies.blogspot.com/2017/10/wrong-answer.html
[119] J Butler, K Anderson, M Supiano, C Weir, "*It Feels Like a Lot of Extra Work: Resident Attitudes About Quality Improvement and Implications for an Effective Learning Healthcare System* (2017). https://www.ncbi.nlm.nih.gov/pubmed/28657555

cells, and avoiding culturing their urine unless they later had signs and symptoms of an infection, in order to lower reportable CAUTI rates (what is not tested is not found, and therefore does not have to be reported).[120]

In contrast to the value-based purchasing incentive are penalties for poor infection control, Section 3008 of the Affordable Care Act created the Hospital-Acquired Conditions Reduction Program, ("HACRP"), effective October 1, 2014.[121] As part of HACRP, the CMS requires acute care facilities to fulfill the CMS's Hospital Inpatient Quality Reporting ("IQR") requirements by reporting certain hospital-acquired infections[122] to the CDC via the NHSN.[123] Based on the NHSN data, hospitals found in the bottom 25% in performance for hospital-acquired condition ("HAC") rates will be subject to a 1% reduction in Medicare payments.[124] Since the CMS began the HACRP, 241 hospitals have been penalized three years in a row.[125]

The underreporting of infection rates may also be attributed to deliberate strategies to game the system for financial gain.[126] Since accurate reporting of high infection rates can result not only in withheld bonuses but also in reduced reimbursement for poor performance, there is a real potential for intentional gaming of reporting to maximize bonuses and reimbursements.[127]

In fact, the CMS and the CDC jointly wrote a letter to reporting hospitals warning of the potential risk to patients when hospitals avoid standard diagnostic practices in order to lower reportable infection rates.[128]When payments are connected to performance measures, it would be especially

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[120] Daniel Diekema, *Rising Stakes for Health Care-Associated Infection Prevention: Implications for the Clinical Microbiology Laboratory* (2017) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5377856/

[121] Centers for Medicare and Medicaid Services, *Hospital-Acquired Condition Reduction Program*, (2017). https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/HAC-Reduction-Program.html

[122] Operational Guidance for Acute Care Hospitals to Report Central Line-Associated Bloodstream Infection (CLABSI) Data to CDC's NHSN for the Purpose of Fulfilling CMS's Hospital Inpatient Quality Reporting (IQR) Requirements https://www.cdc.gov/nhsn/pdfs/cms/Final-ACH-CLABSI-Guidance-2015.pdf

[123] Centers for Disease Control and Prevention, *What is NHSN?* (2015) https://www.cdc.gov/nhsn/about-nhsn/index.html

[124] Centers for Medicare and Medicaid Services, Hospital-*Acquired Condition Reduction Program*, (2017). (Last accessed 11/8/2017) https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/HAC-Reduction-Program.html

[125] Becker's Clinical Leadership and Infection Control*, The 241 Hospitals Punished 3 Years in a Row for High Infection Rates (2017)*, https://www.beckershospitalreview.com/quality/the-241-hospitals-punished-3-years-in-a-row-for-high-infection-rates.html

[126] William Trick, Decision Making During Healthcare-Associated Infection Surveillance: A Rationale for Automation, 57 Clin Inf Dis, 3 at 434 (2013), https://academic.oup.com/cid/article/57/3/434/461013

[127] *Id.*

[128] The Centers for Disease Control and Prevention, *Adherence to the CDC's Infection Definitions and Criteria is Needed to Ensure Accuracy, Completeness, and Comparability of Infection Information*, 1, 1 (2015), https://www.cdc.gov/nhsn/pdfs/cms/NHSN-Reporting-signed.pdf

important to standardize reporting.[129] Inaccurate or inconsistent data analysis or intentional gaming of HAI reporting can cause inappropriate payments or penalties, exposing hospitals to financial loss (if payments are inappropriately withheld) and to false claims liability for bonuses not earned or penalties not paid.[130]

Underreporting of infection rates may also be influenced by Medicare's payment policy for inpatient stays.[131] The inpatient prospective payment system ("IPPS") is a payment system for acute hospitalizations, [132] begun in 1983 by Medicare.[133] Medicare Part A, as authorized by the Social Security Act, reimburses for a myriad of types of hospitalizations, according to their diagnosis-related group (DRG).[134] As its name implies, a prospective payment system is one that pays a predetermined, set amount for a given diagnosis.[135] IPPS incorporates value-based performance ("VBP") and Hospital Acquired Condition Reduction Program ("HACRP") adjustments into its payment.[136]

To begin with, there is a base operating DRG amount which is a wage-adjusted DRG payment[137] plus any applicable new technology add-on payments.[138] Under the value-based performance program, Medicare reduces a participating hospital's base operating DRG payments by 2 percent (as of fiscal year 2017) in order to fund value-based payments.[139] It then turns around and uses achievement and improvement scores across several categories of care, referred to as domains, to

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[129] Shahian, *supra* note 92, at 435.

[130] *Id.*

[131] Centers for Medicare and Medicaid Services, *Acute Inpatient PPS*, 2017. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/
[132] Centers for Medicare and Medicaid Services, *Acute Inpatient PPS*, 2017. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/

[133] Amitahb Chandra, Dhruv Kullar, and Gail Wilensky, *The Economics of Graduate Medical Education* (2014) http://www.nejm.org/doi/pdf/10.1056/NEJMp1402468
[134] Centers for Medicare and Medicaid Services, *Acute Inpatient PPS*, (2017). https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/

[135] Centers for Medicare and Medicaid Services, *Prospective Payment Systems-General Information* (2017), https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ProspMedicareFeeSvcPmtGen/
[136] Department of Health and Human Services, *Acute Care Hospital Inpatient Prospective Payment System* (2016) https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/AcutePaymtSysfctsht.pdf
[137] 42 CFR § 412.160 (2018)
[138] 42 CFR § 412.87 (2018)
[139] Department of Health and Human Services, *Acute Care Hospital Inpatient Prospective Payment System* (2016) https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/AcutePaymtSysfctsht.pdf

generate a total performance score, which determines whether a participating hospital merits a value-based payment, and how much that would be.[140]

The Medicare Prescription Drug Improvement and Modernization Act (MMA), passed in 2003, mandates the Hospital Inpatient Quality Reporting Program.[141] This program requires that hospitals report specified quality measures, in order to be eligible for the annual payment rate update (APU).[142] Hospitals that fail to report these measures are subject to a percentage reduction of the APU.[143]

IV. THE OIG WEIGHS IN ON CMS AND CDC VALIDATION OF HAI RATES

The Office of Inspector General (OIG) is the federal agency that helps prevent fraud and abuse and oversees the CMS.[144] Under the Medicare Prescription Drug, Improvement, and Modernization Act (MMA),[145] The CMS is authorized to pay hospitals a higher annual update to their payment rates for successfully reporting quality measures, using the Hospital Inpatient Quality Reporting Program.[146] The CMS is authorized to validate Inpatient Quality Reporting (IQR) data from hospitals.[147] In a report published in late 2017, the OIG analyzed the CMS validation of Inpatient Quality Reporting (IQR) data for payment year 2016.[148]

For payment year 2016, the CMS audited a random sample of 400 participating hospitals as well as a targeted sample of an additional 49 hospitals (CMS is allowed to include up to 200 hospitals in a targeted sample)[149] and requested medical records from those hospitals. [150] The majority of

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[140] Centers for Medicare & Medicaid Services, *Hospital Value-Based Purchasing* (2015), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Hospital_VBPurchasing_Fact_Sheet_ICN907664.pdf

[141] Centers for Medicare & Medicaid Services, *Hospital Inpatient Quality Reporting Program* (2017). https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalRHQDAPU.html

[142] Centers for Medicare & Medicaid Services, *Hospital Inpatient Quality Reporting Program* (2017). https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalRHQDAPU.html

[143] Quality Improvement Organizations, *Value-Based Purchasing* (2017). http://www.stratishealth.org/providers/vbp.html

[144] Office of Inspector General, *About Us* (Last accessed 11/10/17), https://oig.hhs.gov/about-oig/about-us/index.asp

[145]The Centers for Medicare and Medicaid Services, *Reporting Quality Data For Annual Payment Update* (last accessed April 15, 2018). https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/HospitalMMASection501b.pdf

[146] Centers for Medicare and Medicaid Services, *Hospital Inpatient Quality Reporting Program* (2017), https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalRHQDAPU.html

[147] 42 CFR 412.140(d)(2018)

[148] Levinson, *supra* note 16 at 1.

[149] 77 Fed. Reg. 53552–53 (Aug.31, 2012), as cited in supra note 148

[150] Levinson, *supra* note 17 at 9

hospitals (99 percent) passed Inpatient Quality Reporting ("IQR") validation, and the CMS reduced Medicare payments to the six hospitals that did not pass validation.[151]

In its analysis of the CMS validation, OIG referenced a 2015 joint report by the CMS and the CDC on the accuracy of NHSN reporting, which detailed three ways that hospitals could circumvent the CDC requirements for reporting HAI's: overculturing, underculturing, and adjudication.[152] The joint report acknowledged that each of these schemes have been reported to the CDC by individuals in some healthcare facilities.[153] "Overculturing" refers to repeatedly culturing patients who do not have clinical symptoms of an infection.[154] Overculturing may result in positive results that are connected to a later infection that may truly be hospital acquired, but incorrectly attributed to an infection present at admission.[155] "Underculturing" refers to avoiding testing of patients who have clinical symptoms of an infection.[156] This may result in artificially low infection rates, because what is not found when a patient is not tested will not have to be reported.[157] "Adjudication" refers to the practice of hospital administration or clinical superiors in preventing responsible staff from reporting data to the CDC via the NHSN.[158]

The OIG determined that despite the CMS's previous acknowledgment of reported gaming in its 2015 joint report, the CMS failed to use analytics to choose an appropriate targeted sample.[159] Hospitals chosen to be part of a targeted sample may include hospitals that have abnormal or conflicting data patterns, or rapidly changing data patterns, among other criteria.[160] For instance, certain hospitals would show up as outliers for specific measures when compared to other hospitals, and could be included in a targeted sample for further scrutiny.[161] What the OIG saw instead was that the targeted sample was selected based on failure to report all HAIs, rather than being selected for aberrant data patterns.[162] In fact, the CMS and the CDC used an edit checking

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[151] *Id.*

[152] CDC and CMS, *Adherence to the CDC's Infection Definitions and Criteria is Needed to Ensure Accuracy, Completeness, and Comparability of Infection Information* (joint notice), (2015), as cited in Office of Inspector General, *CMS Validated Hospital Inpatient Quality Reporting Program Data, but Should Use Additional Tools to Identify Gaming* (2017), (last accessed 11/10/17) https://oig.hhs.gov/oei/reports/oei-01-15-00320.pdf

[153] *Id.*

[154] Levinson, *supra* note 17, at 6

[155] *Id.*

[156] *Id.*

[157] *Id.*

[158] *Id.*

[159] *Id*. at 11.

[160] *Id*.

[161] *Id.*

[162] *Id*. at 12.

system to strengthen the quality and accuracy of reporting, rather than identifying abnormal patterns in data.[163] Both the CMS and the CDC acknowledged that getting patient-level data (data that is directly reported to the NHSN, presumably before being "cleaned up" by an edit system), would help better identify outliers and those who are gaming the system.[164]

The OIG likely concluded that the reported rates looked better than they actually were. One reason for this may be that the OIG became aware of subjectivity in hospital reporting from expert stakeholders.[165] Another indicator that could result in skewing of data was the CMS's acknowledgement that direct rather than edited data from NHSN was a superior data set.[166] The OIG concluded its report by recommending that the CMS use analytics when selecting future targeted samples, in order to determine whether hospitals were manipulating reported data on HAIs.[167]

V. UNDERREPORTING INFECTIONS AS BASIS FOR FALSE CLAIMS ACT LIABILITY

The False Claims Act originated during the Civil War to fight fraud against the federal government by suppliers to the Union Army.[168] The original False Claims Act assessed a $2,000 penalty and double the Government's damages against wrongdoers who knowingly presented false claims to the Government for payment.[169] It also allowed relators, those who brought a *qui tam* cause of action (private citizens bringing suit on behalf of the Government), to receive fifty percent of the Government's recovery in successful lawsuits.[170] It has undergone several revisions since it was first enacted in 1863.[171]

To begin with, increased government spending in the 1930s and 1940s opened up more opportunities for fraud by government contractors.[172] This led to "parasitic litigation," in which many individuals could bring separate *qui tam* actions and recover damages against the same

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[163] Id. at 13

[164] Levinson, *supra* note 17, at 11

[165] *Id*. at 7, 10
[166] *Id*. at 13.
[167] *Id*. at 14.
[168] J. Stuart Showalter, *The Law of Healthcare Administration* 527 (7th ed. 2015).
[169] Department of Justice, *The False Claims Act: A Primer* (last accessed 11/21/2017), https://www.justice.gov/sites/default/files/civil/legacy/2011/04/22/C-FRAUDS_FCA_Primer.pdf
[170] Harry Litman and Joseph Zwicker, *A New Practitioner's Guide to the Federal False Claims Act* (Last accessed 11/21/17). https://www.americanbar.org/content/dam/aba/administrative/litigation/materials/sac_2012/25-1_fca_101_presentation.authcheckdam.pdf
[171] Hans von Skapovsky and Brian Walsh, *Correcting False Claims About the New False Claims Act Legislation* (2009), http://www.heritage.org/report/correcting-false-claims-about-the-new-false-claims-act-legislation
[172] *U.S. ex rel.Findley v. FPC-Boron Employees' Club*, 105 F.3d 675 679(D.C.Cir. 1997) (citing CONG.GLOBE, 37TH CONG.,3D SESS.955-56 (1863).

individual.[173] The 1943 provisions forbid *qui tam* litigation if the Government already had information in its possession regarding the claim..[174] The 1943 revisions also cut a relator's share in a successful false claims suit from 50% to 25%.[175]

Another major revision occurred in 1986, when Congress encouraged individuals with knowledge of false claims activity to alert the Government.[176] This was in the wake of the Department of Health and Human Services having a huge increase in the number of fraud cases referred to the Department of Justice for prosecution.[177] The 1986 revision increased the relator's share to 30 percent, and added language to address reverse false claims.[178] At this time, "reverse false claims" referred to representations made to reduce an obligation to pay the government.[179] These statements would be treated as if they were false claims.[180]

Between 1986 and 2008, there were over 10,000 FCA cases filed.[181] Ironically, though approximately only forty percent of the FCA cases were healthcare fraud cases, these cases, in contrast to the remaining FCA cases, resulted in the Government recovering two thirds of the $22 billion it realized from successful prosecution of all FCA cases during this time.[182]

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[173] Christopher Alexion, Note, *Open the Door, Not the Floodgates: Controlling* Qui Tam *Litigation Under the False Claims Act*, 69 WASH & LEE L. REV. 365, 368 (2012).
Christopher M. Alexion, *Open the Door*, *Not the Floodgates: Controlling* Qui Tam *Litigation Under the False Claims* Act, 69 Wash. & LeeL. Rev. 365 (2012), http://scholarlycommons.law.wlu.edu/wlulr/vol69/iss1/8

[174] Charles Doyle, *Qui Tam: The False Claims Act and Related Federal Statutes*, p. 7 (2009). https://fas.org/sgp/crs/misc/R40785.pdf

[175] *Id*.

[176] Christopher Alexion, Note, *Open the Door, Not the Floodgates: Controlling* Qui Tam *Litigation Under the False Claims Act*, 69 WASH & LEE L. REV. 365, 368 (2012).

[177] False Claims Reform Act of 1985, S. REP. No. 345, 99th Cong., 2nd Sess., reprinted in 1986 U.S. CODE CONG. & ADMIN. NEWS 5266, https://www.morganverkamp.com/wp-content/uploads/2015/05/Senate-Report-99-345-FCA.pdf

[178] Tyler Robinson and Roger Clayton, *The Rise of the Reverse False Claim and Proposed Rules from CMS on Reporting and Returning Overpayments* (2014). http://www.iadtc.org/news/152147/Rise-of-the-Reverse-False-Claim--Proposed-Rules-from-CMS-on-Reporting--Returning-Overpayments.htm

[179] *Id*.

[180] *Id.*

[181] Robert Rhoad and Matthew Fortunato, *A Gathering Storm: The New False Claims Act Amendments and Their Impact on Healthcare Fraud Enforcement*, 21 The Health Lawyer, 6, at 18 (2009), https://www.crowell.com/documents/New-False-Claims-Act-Amendments-And-Their-Impact-On-Health-Care-Fraud-Enforcement.pdf

[182] *Id.*

In 2009, Congress passed the Fraud Enforcement and Recovery Act, which resulted in major changes to the reverse false claims provision of the FCA.[183] Importantly, the FERA's amendments to the FCA included imposing liability for knowingly retaining Medicare and Medicaid overpayments.[184] With the newest iteration of the FCA, it is no longer necessary to make a false record or statement to avoid an obligation to pay the Government to have a reverse false claim.[185] Previous judicial interpretation of the 1986 revisions[186] had required a false statement in order to have a reverse false claim.[187] Now, a defendant is liable for a reverse false claim by retaining an overpayment that he is obliged to repay.[188]

A. Elements of a False Claim Cause of Action

To understand what a reverse false claim is, one must begin with understanding the definition of a "false claim." A false claim occurs when a person knowingly makes an untrue statement to get a reward.[189] Defined terms are important when it comes to the False Claims Act. "Knowing" and "knowingly" mean that a person either has knowledge of information, or acts in deliberate ignorance or reckless disregard of whether the information is true or false.[190] "Claim" refers to any demand for payment from the Government.[191] An "obligation" is a duty arising from, among other things, retention of an overpayment.[192] "Material" means having the tendency to influence payment.[193]

The False Claims Act describes those who are subject to penalty for a false claim.[194] Included are those who knowingly: 1) present a false claim;[195] 2) make a false statement in order to get payment for a claim;[196] 3) make a false record material to an obligation to pay the Government or to avoid

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[183] Fraud Enforcement and Recovery Act of 2009, Pub. L. 111-21, S. 386, 123 Stat. 1617

[184] Robert Rhoad and Matthew Fortunato, *A Gathering Storm: The New False Claims Act Amendments and Their Impact on Healthcare Fraud Enforcement*, The Health Lawyer Volume 21, Number 6, p. 18 (2009). Last accessed 11/4/2017 https://www.crowell.com/documents/New-False-Claims-Act-Amendments-And-Their-Impact-On-Health-Care-Fraud-Enforcement.pdf

[185] *Id.*

[186] Harry Litman and Joseph Zwicker, *A New Practitioner's Guide to the Federal False Claims Act* (Last accessed 3/18/18). https://www.americanbar.org/content/dam/aba/administrative/litigation/materials/sac_2012/25-1_fca_101_presentation.authcheckdam.pdf

[187] *See Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 128 S. Ct. 2123, 170 L. Ed. 2d 1030, 2008 U.S. LEXIS 4704, 76 U.S.L.W. 4387, 37 A.L.R. Fed. 2d 773, 21 Fla. L. Weekly Fed. S 300 (Supreme Court held that defendant needs to make false statement in order to be liable for false claims).

[188] Harry Litman and Joseph Zwicker, *A New Practitioner's Guide to the Federal False Claims Act* (Last accessed 3/18/18). https://www.americanbar.org/content/dam/aba/administrative/litigation/materials/sac_2012/25-1_fca_101_presentation.authcheckdam.pdf

[189] False Claim, Black's Law Dictionary Free Online Legal Dictionary (2nd ed. 2017). http://thelawdictionary.org/false-claim/

[190] 31 USC § 3729 (b)(1) (2018).

[191] 31 USC § 3729 (b)(2) (2018).

[192] 31 USC § 3729 (b)(3) (2018).

[193] 31 USC § 3729 (b)(4) (2018).

[194] 31 U.S.C. § 3729 (2018).

[195] 31 U.S.C. § 3729 a(1)(A) (2018).

[196] 31 U.S.C. § 3729 (a)(1)(B) (2018).

an obligation to pay the Government: or 4) conceal or improperly avoid or decrease an obligation to pay the Government. [197] Categories (3) and (4) above refer to "reverse" false claims.[198]

Depending upon the underlying facts, a hospital's intentional underreporting of infection rates to increase prospective payment under the Value-Based Payment Program, to avoid reductions in the annual payment update under the Hospital Acquired Conditions Reduction Program or to avoid having to repay the government for overpayments could be cast as false claims.

B. False Claims: Factually or Legally False

Factually false claims concern billing for goods or services that one has not provided.[199] One example in healthcare is phantom billing, or billing for someone who never received services.[200] Legally false claims concern either express compliance with a condition of payment, or implied compliance by virtue of presenting a claim.[201] An express certification of compliance with the law may accompany a submission of a claim for payment.[202] However, under the FCA liability may also arise from a certification of compliance with the contractual, statutory, and regulatory requirements applicable to those claims that is *implied* by the mere submission of a claim for payment to the government.[203]

VI. *ESCOBAR* AS SEMINAL SUPREME COURT CASE HIGHLIGHTING FALSE CLAIMS LIABILITY UNDER THEORY OF IMPLIED CERTIFICATION

The seminal Supreme Court case on the theory of implied certification under the FCA is *Universal Health Services, Inc. v. United States ex rel. Escobar.*[204] In *Escobar*, the Court stated that implied certification can be a violation of the FCA when a person submits a claim but fails to disclose noncompliance with a contractual, statutory, or regulatory requirement, resulting in a false claim.[205]

Escobar concerned a counseling center that submitted claims for payment but failed to disclose that many of its treating professionals were unlicensed, in violation of Medicaid requirements.[206]

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[197] 31 U.S.C. § 3729 (a)(1)(G) (2018).
[198] 31 U.S.C. § 3729 (a)(1)(G) (2018).
[199] Gregory Glass and Michael Holt, *Implied Certification Under the False Claims Act*, (2011). https://scholarship.law.georgetown.edu/cgi/viewcontent.cgi?article=1641&context=facpub
[200] Greg Freeman, *6 Ways to Avoid Unintentional Medicare Fraud*, (2014). http://www.healthleadersmedia.com/health-plans/6-ways-avoid-unintentional-medicare-fraud#
[201] Glass *supra* note 248.
[202] *United States ex rel. Bierman v. Orthofix Int'l, N.V.*, 113 F. Supp. 3d 414, 2015 U.S. Dist. LEXIS 91692, *420

[203] Ty Howard et al., *False Claims Act: 2016 Year in Review* (2017). https://www.bradley.com/insights/publications/2017/01/false-claims-act-2016-year-in-review
[204] 136 S. Ct. 1989 (U.S. June 16, 2016).
[205] *Universal Health Servs. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 195 L. Ed. 2d 348, 2016 U.S. LEXIS 3920, at *1995, 84 U.S.L.W. 4410, 41 I.E.R. Cas. (BNA) 709, 26 Fla. L. Weekly Fed. S 258

[206] *Id*. at *1997

In this case, respondents claimed that Universal Health Services violated the False Claims Act by submitting reimbursement claims to Medicaid that omitted specific information that would have affected the Government's decision to reimburse.[207] On the other hand, petitioners argued that claims submissions do not involve representations; therefore, nondisclosure of noncompliance with licensure requirements is not actionable as a false claim because there is no special duty to disclose.[208] The Court relied on precedent cited in its decision.[209] Despite upholding implied certification as a basis for FCA liability, the Court remanded the case for further consideration of whether the respondents had successfully pleaded an FCA violation, without determining whether nondisclosure of noncompliance with licensing requirements was material to the Government's decision to pay claims.[210]

Though the Court did not determine whether the petitioner's nondisclosure of noncompliance with licensing requirements was material, it discussed "materiality" at length in *Escobar*.[211] With respect to the False Claims Act, "materiality" means that defendants violate the False Claims Act when they make a misrepresentation that they know is material to the Government's decision to pay.[212] The Court described instances in which misrepresentations were not material: (1)when the Government pays a claim despite knowledge that the presenters violated statutory, regulatory and contractual requirements; or (2) when the Government regularly pays a claim despite knowledge that the presenters violated requirements, and has not changed its position on whether to pay.[213]

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[207] *Id*. at *1993

[208] Id. at *2000.

[209] *See* United States ex rel. Hutcheson v. Blackstone Med., Inc., 647 F.3d 377, 2011 U.S. App. LEXIS 10972 (FCA liability arises when defendant acts knowingly and there is a material defect in the claim. *See Junius Const. Co. v. Cohen*, 257 N.Y. 393, 178 N.E. 672, 1931 N.Y. LEXIS 870 (actionable half-truth when one makes representations about two facts, but fails to mention third fact, and listener believes he has heard whole truth because of two facts). *See Sarvis v. Vt. State Colleges*, 172 Vt. 76, 772 A.2d 494, 2001 Vt. LEXIS 9, 81 Empl. Prac. Dec. (CCH) P40,666 (job applicant makes an actionable misrepresentation by listing former jobs and then retirement, but failing to disclose that "retirement" referred to imprisonment for bank fraud).

[210] *Universal Health Services, supra* note 254, at *2004.

[211] *Id.* at *1996

[212] *Id*.

[213] *Id.* at *2004. But *see* *United States ex rel. Conner v. Salina Reg'l Health Ctr.*, Inc., 543 F.3d 1211, 2008 U.S. App. LEXIS 20808, 71 Fed. R. Serv. 3d (Callaghan) 1266, where Court held that false certifications on a cost report does not equate to a false claim because the certifications were not considered material to the Government's decision to pay.

A recent false claims case discussing materiality and relying on *Escobar* is instructive.[214] *United States v. Salus Rehab* concerns defendants who successfully moved for a new trial after receiving an adverse judgment of almost $350 million, following submission of numerous Medicaid claims from skilled nursing facilities, reflecting upcoding without adequate documentation of comprehensive care plans.[215] In *Salus*, the Court held that since the Government had shown leniency with required documentation, its continued payment of claims was evidence that inadequate documentation was not material to the Government's decision to pay.[216] The *Salus* Court underscored the rigorous requirements of materiality and scienter in its decision.[217] However, this decision's findings as to materiality could be criticized for failing to take into account the government's dilemma when stopping reimbursement results in the discontinuance of services to a large, vulnerable population of elderly, frail individuals because of false claims.[218] Further, the holding is astonishing in light of the defendants' prior history of a systematic scheme of upcoding, backdating, and fabricating billing data.[219]

The CMS requires every Medicare-certified institution to submit an annual cost report to a Medicare Administrative Contractor.[220] Every cost report submitted to Medicare for reimbursement is an implied certification that its preparers have complied with statutory, regulatory, and contractual requirements.[221] Any facet of a cost report that reflects system wide falsification is a misrepresentation of compliance, and can subject a submitting facility to false claims liability.[222]

The CMS also requires every hospital participating in the Hospital IQR Validation Program to submit quarterly templates on chosen HAIs (these vary by fiscal year).[223] Since reporting is

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[214] *United States v. Salus Rehab*., LLC, 2018 U.S. Dist. LEXIS 5148

[215] *Id*. (Receiving payment for inadequate document is arguably comparable to receiving bonuses for failing to report detected HAIs.)

[216] *Id.*

[217] *Id.* at *11

[218] *Id.* at*15, *18

[219] *United States ex. rel. Ruckh v. Genoa Healthcare Consulting, LLC*, 2013 U.S. Dist. LEXIS 195926

[220] Centers for Medicare and Medicaid Services, *Cost Reports* (2018). https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/

[221] *Universal Health Servs., supra note* 257, at *2000

[222] 31 U.S.C. § 3729 (2017).

[223] Rebecca King-Kaprich, *Hospital IQR Validation Program HAI Validation Template Submission* (2016). https://www.qualityreportingcenter.com/wp-content/uploads/2016/07/08012016Hospital-Inpatient-Quality-Reporting-IQR-Validation_edits_notes-revisions_FINAL.508.pdf

connected to up to two percent in reimbursement funding, any system wide falsification of HAI data could subject a reporting facility to false claims under the theory of implied certification.[224]

A. False Reporting and False Claims Liability

Reported decisions reveal that some healthcare systems have been less than forthright in past patterns of reporting. One example is described in *United States v. Bourseau*, where the court found two psychiatric facilities guilty of express and reverse false claims for knowingly submitting incorrect cost reports three years in a row.[225] Another example of misleading reporting patterns occurred in *United States of America, ex rel. Matheny v. Medco Health Solutions*. Here, the court held that the defendants had two instances of reverse false claims: first, when they submitted a false certification of compliance to hide that they were retaining identified overpayments, and second, when they submitted a perfect discovery example, removing all evidence of overpayments, in order to avoid being audited.[226] A third example, *United States ex rel. Duffy v. Lawrence Memorial Hospital*, highlights a hospital's efforts to earn incentive payments under the value-based purchasing system, and avoid penalties under the outpatient quality reporting program, by misrepresenting time intervals between arrival and treatment in an emergency room.[227] This case survived the hospital's motion for summary judgment, with the court stating that it would take a holistic approach in determining whether misrepresenting time intervals was material to the government's decision to pay.[228]

Finally, in *United States ex rel. Worthy v. Eastern Maine Healthcare System*, Jennifer Worthy, a former patient accounts manager, alleged that an outside billing service company instructed coders at a hospital to systematically manipulate claims in order to get them paid, using multiple processes.[229] One process involved falsely adding -59 Modifiers, which are additions to coded services that allow unbundling of charges, and thus cause Medicare to pay more money for services.[230] A second process involved falsely adding G0 codes, which certify that multiple medical visits to the same location were for separate, unrelated reasons, rather than related reasons.[231] G0 codes allow billing for duplicate facility fees, resulting in higher reimbursement than what Medicare should have had to pay.[232] A third process involved deleting accident and

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[224] *Universal Health Servs., supra* note *257*, at *2000

[225] *United States v. Bourseau*, 531 F.3d 1159, 2008 U.S. App. LEXIS 14891

[226] See *United States of America, ex rel. Matheny v. Medco Health Solutions, Inc.*, 671 F.3d 1217 (2012), https://scholar.google.com/scholar_case?case=2507687621598509802&q=reverse+false+claim&hl=en&as_sdt=80006

[227] *United States ex rel. Duffy v. Lawrence Mem'l Hosp.*, 2017 U.S. Dist. LEXIS 105002, *5

[228] *Id*. at *20.

[229] *United States ex rel. Worthy v. Eastern Me. Healthcare Sys*., 2017 U.S. Dist. LEXIS 6556, *14

[230] *Id.* at *15.

[231] *Id.* at *17.

[232] *Id.*

injury information by removing external cause of injury codes (E codes), so that there would be no consideration of whether Medicare was a primary or secondary payer for a claim.[233] Accident and injury information would trigger primary payers to pay first, with Medicare only paying what primary payers have not already paid.[234] Ms. Worthy alleged witnessing the outside billing company pressuring coders to engage in all of the above listed practices.[235] Ms. Worthy also alleged that the outside billing company pressured her to change the discharge status of some patients from discharge to a skilled nursing facility to discharge to home, in order to receive higher Medicare reimbursement.[236] This case is ongoing, having survived several motions to dismiss.[237]

B. "Knowingly" under the False Claims Act

Establishing the scienter requirement ("knowingly") can be elusive.[238] In *United States v. University of Phoenix*, the court held that scienter is established when a person knowingly violates a regulatory requirement with intent to deceive.[239] Innocent or unintentional regulatory violations are not enough to establish false claims liability.[240] In *United States v. Anesthesia Association of Kansas City*, the court held that an ambiguous regulation subject to a reasonable interpretation negates the establishment of scienter.[241] However, in *United States v. Lincare Holdings, Inc.*, the court held that a person may have the requisite scienter necessary for false claims liability, even if a regulation is ambiguous.[242]

In *United States v. United Healthcare Insurance*, a relator brought a *qui tam* suit against United Healthcare, a Medicare Advantage organization, alleging that United Healthcare falsely certified that medical claims it submitted to the CMS were accurate.[243] The court discussed the "ostrich" situation, in which individuals who receive public funds bury their heads in the sand by avoiding asking questions to ascertain whether false claims are being submitted.[244] In fact, 42 C.F.R. § 422.504(l) requires Medicare Advantage organizations to use due diligence in order to certify that

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[233] *Id.* at *18.

[234] *Id.*

[235] *Id.* at *22.

[236] *Id.* at *24.

[237] *Id*. at *111, 112.

[238] Mark Rush, David Kellch, and Kelly Flanigan, *The Circuits are Split: The Ambiguity of a Regulation May Not 'Foreclose a Finding of Scienter' in False Claims Act Cases*, (2017). http://www.klgates.com/the-circuits-are-split--the-ambiguity-of-a-regulation-may-not-foreclose-a-finding-of-scienter-in-false-claims-act-cases-06-27-2017/

[239] *United States v. Univ. of Phoenix*, 461 F.3d 1166, 2006 U.S. App. LEXIS 22568 *1175

[240] *United States v. Univ. of Phoenix*, 461 F.3d 1166, 2006 U.S. App. LEXIS 22568 *1175

[241] *United States v. Anesthesia Association of Kansas City*, No. 15-2420 (8th Cir. 2016) https://cases.justia.com/federal/appellate-courts/ca8/15-2420/15-2420-2016-08-12.pdf?ts=1471015901

[242] *United States v. Lincare Holdings, Inc.,* No. 16-10532 (May 26, 2017), http://media.ca11.uscourts.gov/opinions/pub/files/201610532.pdf.

[243] *United States v. United Healthcare Ins. Co*., 848 F.3d 1161, 2016 U.S. App. LEXIS 22368 *1174

[244] *Id.*

data submitted to Medicare are accurate, complete, and truthful.[245] The court held that anyone submitting Medicare advantage claims should use diligence to determine that what is submitted is accurate.[246] Similarly, anyone responsible for submitting claims to Medicare for payment, preparing IQR templates, or reporting HAIs to the NHSN should use diligence to assure that what they are submitting is accurate, complete, and truthful, in order to avoid false claims liability under a theory of implied certification.[247]

Though there is scarce case law that addresses deliberately underreporting infection rates, some parallels can be drawn. Just as it is wrong to knowingly submit false cost reports, false time intervals, or upcoded documents, knowingly submitting infection rate data to the NHSN, and knowingly submitting cost reports that incorrectly call HAIs POA infections can put a facility at risk of false claims liability. These actions are false claims under a theory of implied certification, and they are reverse false claims if their submission results in an unearned bonus or unassessed penalty.

VII. RECOMMENDATIONS FOR REPORTING PRACTICES TO AVOID FALSE CLAIMS LIABILITY

When resources are finite, it is imperative to maximize the benefit of dollars spent on healthcare. As demonstrated, government payment policies connecting financial incentives to reported infection rates may not be the optimal approach to track and decrease the incidence of hospital-acquired infections. Increasing penalties for substandard performance will likely lead to less forthrightness in reporting, putting patients at risk, and leave institutions susceptible to false claims suits. In examining the reporting practices of other countries, there appears to be a consensus that reporting is necessary, but so are preventive practices.

Recommendations for reporting incidence of hospital-acquired infections in the United States should include the uncoupling of pay for performance and infection rate reporting. The time spent to comply with monthly reporting to the NHSN could be better allocated to preventive practices, such as monitoring handwashing practices. There should also be standardized reporting requirements, using rigorous external validation of data via the National Quality Forum. [248]

One could argue that there should be a tight connection between reporting infection rates and meeting conditions of participation, with zero tolerance for gaming the system. In other words, if a healthcare facility submits claims for payment with the knowledge that they have not been

[245] 42 CFR § 422.504(l):
Certification of data that determine payment. As a condition for receiving a monthly payment under subpart G of this part, the MA organization agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of relevant data that CMS requests. Such data include specified enrollment information and other information that CMS may specify. (42 CFR 422.504(l))

[246] *United*, *supra* note 291 at *1174.

[247] *Universal Health Servs. supra* note 254 at *2000.

[248] Shahian, *supra* note 98 at 436.

truthful in coding HAIs, that facility should be subject to losing participation in Medicare and Medicaid in addition to any FCA fines or penalties. However, for institutions that are critical to the health care safety net, increased technical assistance and corrective action plans should be the focus of enforcement activities.

Finally, in addition to increasing the focus on prevention, government health care policies should lead in standardizing a culture of excellence in clinical practice, such that the best determinations can be made regarding what infections need surveillance, and which tests are best to use to get consistent, reliable, accurate results. Promoting a culture of transparency, rather than incentivizing the gaming of the system, will make patients safer and make it less likely that infection reporting will result in false claims liability.