

# ACHIEVING THE GOALS OF THE VALUE-BASED PURCHASING PROGRAM: DEFINING A STANDARD FOR EXTERNAL DATA USE

SVITLANA MAKOVYIY (LANA)

## ABSTRACT

*In our society, artificial intelligence technology has permeated through every aspect of human life. By the end of 2019, more than 60 million Americans will use some kind of smartwatch, whether a Fitbit or an Apple Watch as a part of their daily routine. Further, over 58% of people currently use a healthcare-related mobile application, such as MyFitnessPal or Nike+ Running. Health and fitness application usage increased by over 330% in the last three years. Unsurprisingly, healthcare-related data is one of the fastest growing and financially valuable data pools in the country, if not worldwide. The volume of data generated is predicted to increase to 2,314 exabytes by 2020. Such data is stored in the Big Data pool with universal interface programming, aimed to enhance interoperability with different health provider systems in the medical community. The absence of a legislative directive, guidance, or a systematic approach to organize vast amounts of continuously incoming data on the front end limits its effectiveness through subsequent utilization. It is more prone to being incomplete, dated, erroneous, or incompatible with the analytic systems into which the data is inputted. This problem is especially pertinent in the context of the Value-Based Purchasing (VBP) Program, where the rate of reimbursement of medical services for Medicare patients depends on production of accurate and reliable data. VBP conditions 90% of its payments on the hospitals' ability to generate data required by the Program. The interconnectedness between VBP's premise, "enhanced patient quality and lower medical costs," and production of accurate data highlights the need for legal action to mitigate risks associated with unstructured healthcare data. Such legal action would at a minimum provide a framework or a set of standards for the kinds of data that may be used by the participating VBP hospitals to ensure accurate reporting and the maximization of healthcare analytics. Finally, hospitals nationwide have an independent incentive for acquiring reliable and relevant data to integrate as part of their network to lower actual hospital costs, as Medicare reimbursement was \$53.9 billion short in 2017 among the VBP Program providers.*

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## I. OVERVIEW: THE ROLE OF HEALTHCARE DATA IN THE VALUE-BASED PURCHASING PROGRAM

In today's technology-driven world medical providers and administrators have access to numerous quantities of healthcare data, which includes electronic health records, administrative and claims data, patient and disease registries, health surveys, and clinical trials data.<sup>1</sup> Physicians are increasingly relying on data for diagnostic and prognostic stages of patient care nationwide.<sup>2</sup> Administrators<sup>3</sup> utilize data generated within their own entities to satisfy the requirements set forth by the Value-Based Purchasing (VBP) Program, a federal reimbursement system. Such data is collected during the course of ongoing patient care or as a part of a clinical trial program.<sup>4</sup> While this institution-specific data may help a single provider identify some of its flaws, it is unable to provide comprehensive insight that the institution requires for long-term success in enhancing quality of care and decreasing costs. As a result, administrators turn to the use of external data drawn from the Big Data pool to fill the missing puzzle pieces.

All healthcare-related data is accumulated in the Big Data pool, also known as the Fast Healthcare Interoperability Resource. The Big Data pool is equipped with a universal set of interface systems, which makes it interoperable with virtually any medical provider system. Such compatibility facilitates continuous exchange, interpretation, and use of the healthcare

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<sup>1</sup> See *Data Resources in the Health Sciences*, HEALTH SCIENCE LIBRARY: UNIVERSITY OF WASHINGTON, <http://guides.lib.uw.edu/hsl/data/findclin>. (last visited Apr. 15, 2019).

<sup>2</sup> See Melisande Rouger, *First quantitative AI tools for medical imaging receive clearance*, HEALTHCARE IT NEWS (Mar. 11, 2019, 11:30 AM), <https://www.healthcareitnews.com/news/first-quantitative-ai-tools-medical-imaging-receive-clearance>.

<sup>3</sup> *Health Administrator*, EXPLOREHEALTHCAREERS.ORG, <https://explorehealthcareers.org/career/health-administration-management/health-administrator/>. (last visited Apr. 15, 2019). Unlike physicians, health administrators do not directly interact with patients on a daily basis. Rather, they focus on shaping internal policies to improve patient care on an organizational level. *Id.* Members of administrative staff work in different departments, such as: quality review, risk management, patient advocacy, information technology support, utilization review, and managed care. *Id.*

<sup>4</sup> See *Data Resources in the Health Sciences*, *supra* note 1.

information technology (HIT) across a spectrum of healthcare organizations.<sup>5</sup> The enactment of the American Recovery and Reinvestment Act (ARRA) in 2009 mandated healthcare providers switch from hardcopy to electronic records. This transition is a leading force in helping healthcare professionals recognize the value of data collection. The digitization of health records also helped the industry recognize the value in interoperability – for the first time, medical professionals were able to access a patient’s chart online and keep track of all patients’ visits at any affiliated institution.<sup>6</sup>

Federal law recognizes that for healthcare data to evolve, it requires interoperability. With the modernization of electronic records and the increased shift towards collecting external data, federal law enacted exceptions to shield physicians from civil liability should they choose to exchange medical data with certain entities.<sup>7</sup> That federal authority is Stark Law. It is a prominent fraud and abuse statute that prohibits physicians from referring Medicare patients to entities that those physicians have a financial interest in.<sup>8</sup> Stark Law preserves the fluidity of healthcare data exchange and use by articulating three distinct exceptions, which in the aggregate enable physicians to access, share, and exchange electronic records and related patient information to improve the quality of care.<sup>9</sup> Although only hospitals and physicians within the

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<sup>5</sup> *What Is Interoperability?*, CARECLOUD, <https://www.carecloud.com/continuum/what-is-interoperability/>. (last visited Apr. 15, 2019).

<sup>6</sup> *Id.*

<sup>7</sup> *See* 42 C.F.R. §§ 411.357(u)-(w).

<sup>8</sup> *See* 42 C.F.R. § 411.354(a)(1)(i).

<sup>9</sup> *See* 42 C.F.R. §§ 411.357(u)-(w). The three exceptions are: community-wide health information systems exception, electronic prescribing items and services exception, and electronic health records items and services exception. *See id.* A physician’s action that falls under these exceptions does not constitute a financial relationship. *See id.*

network can access and use the data, Stark Law does not limit the scope of data that can be accessed as part of interoperability to continue expanding the Big Data pool.<sup>10</sup>

Today, hospital administrators have their in-house information technicians draw from the Big Data pool, or retain third-party software providers who provide pre-selected sub-groups of data to choose from. Unfortunately, not all data is created equal, and due to the enormous volume of data generated daily, private party providers and independent programmers fall short of ascribing healthcare data into specialized, compatible, clean, and continuously updated categories. As a result, administrators are unable to get sufficiently customizable data, which would help limit the risk of error by accounting for an entity's unique business model and objectives. Consequentially, physicians, administrators, and developers of the healthcare analytics fall short of maximizing the data's potential, particularly in the context of Value-Based Purchasing (VBP) Program, the current federal framework for medical service reimbursement.

## II. THE CHALLENGES OF INTEGRATING INTERNAL AND EXTERNAL DATA WITHIN HEALTHCARE ANALYTICS

Today, healthcare analytics, or a series of software programs, are employed by individual hospitals or hospital systems to measure, assess, and improve quality and performance of a health delivery system. A health delivery system produces vast amounts of data. That data varies in significance and meaning, because it encompasses direct medical care provided by physicians and nurses, as well as any interaction a patient has with a social worker, a security guard, or any other staff member. Healthcare analytics transform a baseline, or internally-generated data into a

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<sup>10</sup> See 42 C.F.R. §§ 411.357(v)(1), (5).

series of insightful statistical outcomes, which reveal what has occurred, what is occurring and why, and what is likely to occur next in a health delivery system.<sup>11</sup>

The internally-generated, or raw data is primarily collected from claims and cost data, pharmaceutical data, clinical data, and patient behavior data.<sup>12</sup> The healthcare analytics' key function is to convert raw data into an interactive intelligence code. To comply with the Value-Based Purchasing (VBP) Program, the intelligence code groups the raw data into one of the six mandatory measures set forth by the Secretary of Health and Human Services. The grouping is primarily based on variable commonalities and relevancy to each of the six measures: mortality and complications, health-associated infections, patient safety, patient experience, admitting process, and cost efficiency.<sup>13</sup>

Analytics can also help identify and categorize patient populations as high, medium, or low risk based on ability to pay, severity of illness, and risk of readmission.<sup>14</sup> This enables hospitals to tailor unique treatment plans which patients would be more likely to follow after discharge. A hospital can also turn to analytics to determine whether there is correlation between two concurrent events. For instance, a hospital's survey shows a sudden drop in patient satisfaction in the intensive care unit (ICU), which also experienced an increase in central line infections. That hospital will turn to analytics to understand whether there is a correlation between the two events and what can be done prospectively to avert central line-related

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<sup>11</sup> See Trevor L. Strome, *HEALTHCARE ANALYTICS FOR QUALITY AND PERFORMANCE IMPROVEMENT* 19 (John Wiley & Sons, Inc., 1st ed. 2013).

<sup>12</sup> See *id.* at 95.

<sup>13</sup> See *The Hospital Value-Based Purchasing (VBP) Program*, CENTERS FOR MEDICARE & MEDICAID SERVICES, <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/HVBP/Hospital-Value-Based-Purchasing.html>. (last modified Aug. 2, 2018, 12:02PM).

<sup>14</sup> See Rose Higgins, *5 Ways To Use Data & Advanced Analytics For Value-Based Care Success*, HEALTHLEADERS (Sep. 27, 2017), <https://www.healthleadersmedia.com/strategy/5-ways-use-data-advanced-analytics-value-based-care-success>.

infections or mitigate patient dissatisfaction rates even if such infections occur.<sup>15</sup> The use of external data from the Big Data pool would help identify other hospitals with similar issues and reveal their reactive action plans.

Alternatively, imagine a forty-five-year-old female patient enters the emergency room in Jacksonville, Florida, suffering from a broken neck. During assessment, doctors determine that surgery is required to repair her injuries. Upon successful completion of the procedure, the patient develops a life-threatening infection linked to inadequate sterilization of surgical instruments. The hospital records and saves this information as a part of patient outcome data. Every patient profile and outcome is then used to generate internal data per department. The primary goals of hospitals, which mirror those of the VBP Program, is to improve patient care and minimize medical costs.

The VBP Program uses financial incentives to reward hospitals for implementing policies that improve quality of care for patients and decrease costs per patient for the hospital. When the hospital in Jacksonville conducts a case-study of patients similar to our forty-five-year-old female in order to prevent or limit the occurrence of similar outcomes in the future, the hospital's internal data is insufficient to identify the steps necessary to avert similar problems among future patients. The hospital turns to the Big Data pool to help fill in the gaps. For the external data to be effective in this case-study, the hospital needs variables specific to the patient population it serves. These variables may account for the primary conditions patients sought treatment for, age, gender, concurrent diseases, and geographic area. There is no system or a requirement in place that would help the data preserve its key variables once it enters the Big Data pool. As a result, such data exists predominantly in an incomplete and de-identified form.

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<sup>15</sup> See Strome, *supra* note 11 at 18.

Healthcare entities often have no choice but to use incomplete data gathered from the broad categories of the Big Data pool to create internal profiles. They are used to identify, monitor, and predict patients' complications and readmission rates. The rates of complications and readmissions are then reported to the Centers for Medicare & Medicaid (CMS), which use their own rubric to determine whether the designated healthcare entity satisfied its benchmark for minimum quality improvement. The quality rating that a provider receives is directly proportional to the rate of reimbursement at the end of the fiscal year. Due to an absence of a centralized or individually monitored system which would help gather, organize, and filter health-related data before it enters the Big Data pool, outgoing data is often incomplete, incompatible, and in conflict with existing data.

Healthcare data is predicted to exceed 2,314 exabytes by 2020<sup>16</sup> and be valued at \$68.75 billion by the end of 2025 (compared to an estimated \$14.25 billion in 2017). This rapidly expanding universe of unstructured data in size and value emphasizes the urgency to organize data to help maximize its utilization potential in the future.<sup>17</sup> An aggregate surge in demand for analysis of structured and unstructured health data contributes to the increase in the data's market growth.<sup>18</sup> In the VBP Program, data-driven outcomes and performance structure patient care and determine reimbursement figures. Hence, we need either a more uniform data collection method at the onset or a greater federal oversight to help sustain the underlying goals of the VBP Program.

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<sup>16</sup> See Bhavya Banga, *Global Big Data in Healthcare Market to Reach \$68.75 Billion by 2025, Reports BIS Research*, PRNEWswire (Mar. 28, 2018, 7:30PM), <https://www.prnewswire.com/news-releases/global-big-data-in-healthcare-market-to-reach-6875-billion-by-2025-reports-bis-research-678151823.html>.

<sup>17</sup> See *id.*

<sup>18</sup> See Fred Donovan, *Healthcare Big Data Analytics Market to See 22% CAGR Through 2023*, HITINFRASTRUCTURE (Jan. 8, 2019), <https://hitinfrastructure.com/news/healthcare-big-data-analytics-market-to-see-22-cagr-through-2023>.



### III. WHAT IS BIG DATA IN HEALTHCARE AND ITS ORIGINS

The healthcare industry is one of the fastest-growing segments of the digital universe, expanding at a 48% rate per year, compared to a 40% rate per year of overall digital growth.<sup>19</sup> Healthcare relies heavily on a wide scope of data-producing sources to continuously expand its Big Data pool. The Big Data pool refers to the vast quantities of information created through digitization and consolidation of targeted health-related data by the analytics technologies.<sup>20</sup> The modern approach to healthcare prioritizes preventative patient care. Hence, for the healthcare analytics systems to be effective, this approach requires diverse sources of data to facilitate machine learning. Some of these vital sources include the Internet of Things, Electronic Medical Records/Electronic Health Records (EMR/EHR), insurance providers, computerized physician order entry (CPOE), clinical decision support systems, such as doctors' notes, genome project, clinical trials, and even social media.

The healthcare industry has long recognized that the Internet of Things (IoT) generates valuable data, because its sources originate directly from people's routine use.<sup>21</sup> Ideally, this would help data remain up-to-date, relevant, and reflective of modern trends. One such source of the IoT is "wearables," such as Fitbit and Apple Watch, which can track people's heart rate, weight, activity and stress levels.<sup>22</sup> In addition to wearables, mobile applications such as

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<sup>19</sup> See *The Digital Universe Driving Data Growth in Healthcare*, VERTICAL INDUSTRY BRIEF (2014), <https://www.emc.com/analyst-report/digital-universe-healthcare-vertical-report-ar.pdf>.

<sup>20</sup> See Mona Lebid, *12 Examples of Big Data Analytics In Healthcare That Can Save People*, DATAPINE (Jul. 18, 2018), <https://www.datapine.com/blog/big-data-examples-in-healthcare/>.

<sup>21</sup> See *Health and fitness app usage "grew 330% in just 3 years"*, NETIMPERATIVE (Sep. 13, 2017), <http://www.netimperative.com/2017/09/health-fitness-app-usage-grew-330-just-3-years/>. Health and fitness application usage increased by over 330% in the last three years. *See id.*

<sup>22</sup> See Steven Musil, *One in 10 American adults expected to have a smartwatch next year*, CNET (Dec. 13, 2018, 3:00 AM), <https://www.cnet.com/news/one-in-10-american-adults-expected-to-have-a-smartwatch-next-year/>. By the end of 2019, more than 60 million Americans will use some kind of smartwatch. *See id.*

AliveCor Heart Monitor and medical devices provide an even greater insight into an individual's diagnosed condition.<sup>23</sup> They do so by collecting electrocardiogram strips, pulse oximeters, glucose and even oxygen levels on exertion. In 2018, mobile users had access to approximately 250,000 fitness and health applications.<sup>24</sup> This does not account for an additional 1,300 applications devoted to mindfulness and meditation, which the healthcare industry also utilizes.<sup>25</sup>

AliveCor is an artificial intelligence and medical device company, which manufactures the first Food and Drug Administration approved electrocardiogram software compatible with Apple devices. AliveCor is a pioneer in helping patients detect cardiac abnormalities in their early stages. Unsurprisingly, at the end of 2017, the company helped customers record more than 20 million electrocardiograms (EKGs).<sup>26</sup> A healthcare application typically requires its users to create a "health profile," which includes: name, e-mail, date of birth, gender, smoking status, height, and weight. More specialized applications, such as AliveCor Heart Monitor, encourages users to also record and continually update activity levels, medications, medical conditions, and symptoms of dizziness or weakness.<sup>27</sup> This allows the company to track the correlation between physical activity, medication dosage, and EKG results. Although AliveCor does not sell any data that it receives from its users, it releases de-identified EKG recordings for clinical research and

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<sup>23</sup> See Paul Krebs & Dustin T Duncan, *Health App Use Among US Mobile Phone Owners: A National Survey*, 3(4) JMIR MHEALTH UHEALTH 1 (2015). Over 58% of people currently use a healthcare-related mobile application. See *id.*

<sup>24</sup> *There are 250,000 fitness and health apps – but little evidence they work*, ABC NEWS (May 16, 2018, 10:39 PM), <https://www.abc.net.au/news/2018-05-17/mhealth-apps-wellness-and-fitness-apps-not-always-proven-to-work/9758720>.

<sup>25</sup> *There are more than 1,300 apps dedicated to mindfulness and meditation*, THE WEEK (Feb. 16, 2017), <https://theweek.com/speedreads/835657/exinterior-secretary-ryan-zinke-promises-new-job-mining-company-not-conflict-interest>.

<sup>26</sup> See *AliveCor*, FAST COMPANY, <https://www.fastcompany.com/company/alivecor>. (last visited Apr. 15, 2019).

<sup>27</sup> See *What information do you collect?*, ALIVECOR ZENDESK, <https://alivecor.zendesk.com/hc/en-us/articles/115015721007--What-information-do-you-collect->. (last updated 2018).

internal improvements.<sup>28</sup> It also grants to external contractors, such as medical institutions and vendors, access to all information other than identifiable recordings and health history.<sup>29</sup> Because AliveCor and health applications alike often release only partial profiles of consumer data, the Big Data pool continues to overflow with incomplete and frequently overlapping data. Many mobile applications do not limit themselves to collecting healthcare data only on their platforms. A staggering number of widely-used services, like MyFitnessPal or Nike+ Running collects, stores, and shares information not only retrieved from its main platform, but also from the users' accounts linked to Facebook.<sup>30</sup> The healthcare industry values data originated from social media because it often provides demographic insights, such as address, region, and marital status.<sup>31</sup> Similarly to AliveCor, MyFitnessPal tailors the kind of data it shares to who requests it – an affiliated medical institution and a research organization will receive different sets of data. As a result, due to the lack of a universal data collecting system, federal oversight, or a mechanism that would prioritize and pre-categorize external data before its exchange into the interoperability pool, the Big Data universe continues to face challenges in creating coherent and compatible data strands.

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<sup>28</sup> See *Do you sell my data?*, ALIVECOR ZENDESK, <https://alivecor.zendesk.com/hc/en-us/articles/115015720907-Do-you-sell-my-data->. (last updated 2018).

<sup>29</sup> See *Do any third party vendors have access to user information?*, ALIVECOR ZENDESK, <https://alivecor.zendesk.com/hc/en-us/articles/115015720967-Do-any-third-party-vendors-have-access-to-user-information->. (last updated 2018).

<sup>30</sup> See *What is Personal Data and what Personal Data does Under Armour collect about me?*, MYFITNESSPAL, <https://myfitnesspal.desk.com/customer/en-portal/articles/2935213-what-is-personal-data-and-what-personal-data-does-under-armour-collect-about-me->. (last updated May 16, 2018, 10:24AM).

<sup>31</sup> See *id.*

#### IV. FEDERAL FRAMEWORK OF THE VALUE-BASED PURCHASING PROGRAM

##### UNDER THE SOCIAL SECURITY ACT

The Social Security Act (“the law”) codifies in Section 1886(o) the Value-Based Purchasing (VBP) Program, which hospitals must follow to remain in compliance with federal law. The VBP Program is designed to use financial incentives to reward hospitals for implementing policies that improve overall quality of acute inpatient care. However, a hospital receives reimbursement for treatment of Medicare beneficiaries in proportion to the quality of treatment of its entire patient population. The five main goals of the VBP Program are: limit healthcare errors, use evidence-based care to improve patient outcomes by decreasing rates of complications and readmissions, enhance patient experience, increase provider transparency, and lower healthcare costs.<sup>32</sup> Out of the total of 6,210 hospitals in the United States,<sup>33</sup> over 3,000 hospitals were enrolled into the VBP Program in 2018.<sup>34</sup> The VBP Program’s ultimate power rests on its ability to structure the hospitals’ approach to their patient care delivery systems network-wide.

The law recognizes the risks associated with using the VBP Program because it relies on the hospitals’ ability to generate and report data as an affirmative measure of quality improvement. As a result, the law goes to great lengths to outline the criteria of who can participate in the program and which quality controls must be used to mitigate the risk of error the data will likely produce. The Centers for Medicare & Medicaid (CMS), the federal agency

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<sup>32</sup> See The Hospital Value-Based Purchasing (VBP) Program, *supra* note 13.

<sup>33</sup> See *Fast Facts on U.S. Hospitals, 2019*, AMERICAN HOSPITAL ASSOCIATION, <https://www.aha.org/statistics/fast-facts-us-hospitals>. (last updated Jan. 2019). The total number of hospitals is 6,210 and they encompass: nongovernmental not-for-profit community hospitals, for-profit community hospitals, state and local government community hospitals, federal government hospitals, nonfederal psychiatric hospitals, and other. See *id.*

<sup>34</sup> See *Hospital Value-Based Purchasing*, AMERICAN HOSPITAL ASSOCIATION, <https://www.aha.org/hospital-value-based-purchasing/home>. (last visited Apr. 15, 2019).

administering the VBP Program, also put in safeguards to mitigate the risk of data-related error. CMS deliberately collects data from the participating hospitals by region. This approach is designed to enhance accuracy of CMS review when it compares the reported data from different hospitals.

Since hospitals compete for the highest quality improvement score in order to receive the highest payment percentage, a region-specific comparison is essential to lower the likelihood of skewed outcomes. The external variables which skew the outcomes if left unaccounted for in the data collection process include: patient demographics, accessibility to healthcare, size of the institution, annual revenue, and specialization. If a public hospital is serving a disproportionately greater number of at-risk patients, such as a city's homeless population, that hospital would naturally have greater readmission rates because of patient-specific risk factors, not its quality of care. This variable must be accounted for to ensure that the readmission rates will not be disproportionately skewed in favor of a private hospital, which only treats insured patients who are more likely to seek check-ups that prevent readmission and complications. Although the law recognizes fluctuations among hospital-generated or internal data, it falls short of accounting for the pillar of the VBP Program – the externally-generated data, which participating hospitals integrate and rely on to reform their healthcare delivery methods.

The law limits which hospitals may participate in the VBP Program and sets out guidelines hospitals must follow when setting up their own internal data collection programs to assess quality of care. Currently, this law governs over 3,000 hospitals across the country.<sup>35</sup> To qualify, a hospital must satisfy a safety benchmark and retain a minimum number of patient

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<sup>35</sup> See *Hospital Value-Based Purchasing*, (citing Medicare Learning Network), CENTERS FOR MEDICARE & MEDICAID SERVICES, [https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Hospital\\_VBPurchasing\\_Fact\\_Sheet\\_ICN907664.pdf](https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Hospital_VBPurchasing_Fact_Sheet_ICN907664.pdf). (last modified Sep. 2017).

cases during a fiscal period.<sup>36</sup> Further, the qualifying hospitals must be sophisticated acute care providers and located in quasi-metropolitan areas in order to meet the minimum case load requirement.<sup>37</sup> Given that the qualifying hospitals constitute advanced facilities serving a diverse group of patients, the necessity to integrate data which guarantees compatibility with the hospitals' needs is essential to comply not only with the goals of the VBP Program, but with the law itself. Approximately 70% of hospitals in the United States are located in quasi-metropolitan or metropolitan areas.<sup>38</sup> As the number of participants in the VBP Program continues to grow, hospitals across the country will begin to recognize the importance of receiving data that is compatible with their unique demographics, budgeting, current procedures, and resource. As a result, the aggregate demand for clean, structured, and accurate data will surge.

Although the law currently remains silent on the importance of identifying healthcare data's external sources and degree of compatibility, it recognizes that data recorded within the hospitals can be biased and insufficient to accurately convey the hospitals' quality performance. As a result, the law sets in place several safeguards to limit the probability of erroneous outcomes, especially when the VBP Program compares quality measure outcomes among a handful of competing hospitals. The Secretary of Health and Human Services ("the Secretary") is given deference to adjust quality efficiency measures for the VBP Program based on age, sex, race, severity of illness, "and other factors that the Secretary determines appropriate."<sup>39</sup> Efficiency measures play an important role, because their absence can disqualify a hospital from

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<sup>36</sup> See 42 U.S.C. §§ 1395ww(o)(1)(C)(ii)(II), (III), (IV).

<sup>37</sup> See *id.*

<sup>38</sup> See Fast Facts on U.S. Hospitals, 2019, *supra* note 33.

<sup>39</sup> See 42 U.S.C. § 1395ww(o)(2)(B)(ii).

eligibility to participate in the VBP Program.<sup>40</sup> Every measure must be used in connection with the service provided, otherwise the statute will not deem it as valid.<sup>41</sup> In other words, for every piece of internal data to be validated, the VBP Program must be able to identify and link it to its source. The Secretary further establishes performance standards,<sup>42</sup> which include levels of achievement and improvement. Additional safeguards to mitigate volatile and inaccurate data include the Secretary's ability to change performance standards every fiscal year. The extent of change is also subject to the Secretary's complete discretion.

The performance measures are a set of scaled factors that are used to measure the hospitals' quality improvement. Although the law requires the usage of uniform set of performance measures, the Secretary exercises discretion when choosing them. Currently, the measures used in the VBP Program are: mortality and complications, health-associated infections, patient safety, patient experience, admitting process, and cost efficiency.<sup>43</sup> The hospitals often face challenges in creating a system that would succeed at accurately assigning a measure to a real-life event occurring on the unit. An effective system requires a hospital to develop a systematic and uniform mechanism that collects and uses that data to accurately assign a numerical measure to those real events at that hospital. Given this added degree of complexity that the hospitals must comply with when structuring their data collection and reporting, the Secretary must give the participating hospitals a 60-day notice in case of a change.<sup>44</sup> If the

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<sup>40</sup> See The Hospital Value-Based Purchasing (VBP) Program, *supra* note 13. Some of the common measures used in the Hospital VBP Program are: mortality and complications, healthcare-associated infections, patient safety, patient experience, process, and efficiency and cost reduction. *See id.*

<sup>41</sup> See 42 U.S.C. § 1395ww(o)(2)(C)(ii).

<sup>42</sup> See 42 U.S.C. §§ 1395ww(o)(3)(A), (B).

<sup>43</sup> See The Hospital Value-Based Purchasing (VBP) Program, *supra* note 13.

<sup>44</sup> See 42 U.S.C. § 1395ww(o)(3)(C).

Secretary decides to change one or more of the performance standards, a hospital would be required to integrate the change into its data analytics system. Such process requires retention of specialized software engineers, which would be very costly for the hospital. As a result, such amendments are rare. Although the statute provides some guidance for the degree to which the Secretary can deviate from existing to new performance measures, it fails to provide the hospitals with a uniform method of data collection, both internal and external, to enhance the accuracy of final reports.<sup>45</sup> The longevity and success of the VBP Program rests on the hospitals' ability to accurately report the efficiency and performance measures, which are ambiguously outlined by the law. This is a difficult task given each measure could reflect numerous variables. Due to the absence of universal guidance, each hospital may conduct its reporting through the use of internal and external data in a variety of ways.

#### V. ADMINISTRATION AND OVERSIGHT OF THE VALUE-BASED PURCHASING PROGRAM

As evidenced by a comprehensive set of provisions within the Social Security Act, the Value-Based Purchasing (VBP) Program is a complex system consisting of multiple sets of efficiency and performance measures the qualifying hospitals are required to report in order to get reimbursed in-part or in-full for their services. The hospital may earn two scores (one for achievement and one for improvement) for each of the six measures: mortality and complications, healthcare-associated infections, patient safety, patient experience, process, and efficiency and cost reduction.<sup>46</sup> Each of the two scores are calculated based on how well a hospital performs in comparison to another hospital and how much a hospital has improved compared to its own performance baseline at the beginning of the fiscal year. This necessitates

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<sup>45</sup> See 42 U.S.C. §§ 1395ww(o)(4), (5), (6).

<sup>46</sup> See The Hospital Value-Based Purchasing (VBP) Program, *supra* note 13.



hospitals to use data-reporting systems that accurately depict internal operations and account for outliers, which may interfere with an accurate comparison to another hospital. Based on the aggregate score a hospital receives, or the Total Performance Score, the law specifies the corresponding percentage for Medicare reimbursement.<sup>47</sup> The net result of the percentage of reimbursement is then applied to an additional Medicare severity diagnosis-related group (MS-DRG), a base payment distributed in addition to the VBP Program payment, at the end of each fiscal year, which amounts to the total amount of annual payment.<sup>48</sup>

During the 2019 fiscal year, the Secretary of Health and Human Services announced that the Total Performance Score will be derived from the identical measures as in 2018.<sup>49</sup> This helps hospitals limit expenses and sustain uniformity in the existing data collection system. However, simply not changing the six reporting measures is not enough. These domains (mortality and complications, healthcare-associated infections, patient safety, patient experience, process, and efficiency and cost reduction)<sup>50</sup> remain broad. Hospitals continue to face challenges that prevail as a result of integrating unstructured data, the use of which is necessary to increase the annual quality performance from a hospital's baseline mark. Hospitals do not have authority or guidance they can turn to that structures this intricate yet unguided data-collection process. Currently, the law shifts the burden onto hospitals to find a system that works to accurately illustrate quality improvement through qualitative and quantitative reports.

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<sup>47</sup> *See id.*

<sup>48</sup> *See id.*

<sup>49</sup> *See Total Performance Score information.* MEDICARE.GOV | HOSPITAL COMPARE, <https://www.medicare.gov/hospitalcompare/data/total-performance-scores.html>. (last visited Apr. 15, 2019).

<sup>50</sup> *See The Hospital Value-Based Purchasing (VBP) Program, supra* note 13.

To ensure hospitals maintain compliance with the intricacies of the law, the Social Security Act delegated administrative oversight of the VBP Program to the Centers for Medicare & Medicaid (CMS). CMS is the federal agency housed in the U.S. Department of Health and Human Services, which oversees compliance with the VBP Program and issues compensation to hospitals.<sup>51</sup> To facilitate uniform compliance and foster efficient communication between the providers and the agency, CMS officers are housed in ten Regional Offices (ROs), each with a unique function.<sup>52</sup> The agency finds it particularly important to oversee the VBP Program on the regional level, because the quality measures hospitals report vary significantly based on their geographic location. Although CMS oversees the VBP Program on regional levels, the lack of guidance during the initial stages of data collection will continue to increase the risk of error, given the astronomical rates of healthcare data production. This may leave hospitals with disproportionate reimbursement rates and an inability to gain accurate insight into the quality of employees' performance. With a lack of clean, reliable, compatible, and identifiable data which would allow hospitals to assess their quality of care, the hospitals will face difficulty in implementing effective policies that will mitigate the cost of care.

## VI. WHY GENERATION OF ACCURATE DATA IS KEY TO A HOSPITAL'S FINANCIAL STABILITY

As outlined above, the use of data plays a critical role in the Value-Based Purchasing (VBP) Program because the Program is very outcome driven. The Centers for Medicare & Medicaid (CMS) conducts annual reviews of the hospitals' data reports and based on those

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<sup>51</sup> See *About CMS*, CENTERS FOR MEDICARE & MEDICAID SERVICES, <https://www.cms.gov/about-cms/about-cms.html>. (last visited Apr. 15, 2019).

<sup>52</sup> See *id.* Regional Offices (ROs) are located in Boston, New York, Philadelphia, Kansas City, Denver, San Francisco, Atlanta, and Dallas. See *id.*

outcomes allocates payments. The total value-based incentive payment amount for the participating hospitals will be over \$1.9 billion for 2019 fiscal year.<sup>53</sup> The rate of reimbursement is based on the Total Performance Score (TPS), calculated as the sum of four domains: clinical care, patient safety, person and community engagement, and efficiency and cost reduction. A hospital may receive two scores per individual measure under the four domains: one for achievement and one for improvement.<sup>54</sup> Similarly to the Social Security Act, CMS does not set parameters for hospitals to follow when choosing variables (such as age, gender, race, demographic, family history, genome, etc.) to translate each of the four measures into a quantitative score. With CMS announcing that it will increase Medicare payments by 55% in 2019,<sup>55</sup> the need for compatible, clean, and relevant data is even higher to ensure that hospitals are able to gain accurate insight into their internal operations.

The CMS's rate of reimbursement for services plays a vital role in predicting a hospital's profits and prospective growth. Uncompensated inpatient care for which hospitals are unable to collect payment is known as the bad debt. Although the ratio between hospital annual billing charges nationwide and the actual payment received from CMS rose to 3.5 to 1 in 2015 from less than 2 to 1 in 1996, hospitals learned to mitigate adverse consequences of bad debt in three main ways.<sup>56</sup> The hospitals may: apply admitted patients for emergency Medicaid, implement

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<sup>53</sup> See *CMS Hospital Value-Based Purchasing Program Results for Fiscal Year 2019*, (citing Newsroom), CENTERS FOR MEDICARE & MEDICAID SERVICES (Dec. 3, 2018), <https://www.cms.gov/newsroom/fact-sheets/cms-hospital-value-based-purchasing-program-results-fiscal-year-2019>.

<sup>54</sup> See *The Hospital Value-Based Purchasing (VBP) Program*, *supra* note 13.

<sup>55</sup> See *CMS Hospital Value-Based Purchasing Program Results for Fiscal Year 2019*, *supra* note 53.

<sup>56</sup> See Jacqueline LaPointe, *Medicare, Medicaid Reimbursement \$76.8B Under Hospital Costs*, REVCYCLE INTELLIGENCE (Jan. 7, 2019), <https://revcycleintelligence.com/news/medicare-medicare-reimbursement-76.8b-under-hospital-costs>. Medicare reimbursement was \$53.9 billion short in 2017 among the VBP Program participants. See *id.*

aggressive utilization reviews, or receive a disproportionate share of funds.<sup>57</sup> Unfortunately, these safeguards are not enough to shield hospitals from disproportionate reimbursement rates, attributed to the volatile outcomes that the use of external data produces. CMS guidance materials, similarly to the Social Security Act, primarily focus on the structure of the VBP Program, as opposed to furnishing hospitals with guidance on the kind of data they should use to maximize the Program's goals. CMS regional offices also fail to raise awareness about the danger of integrating unstructured data into evaluating quality reports and adjusting future delivery approaches. Hospitals need to be made aware that the healthcare data that enters the Big Data pool is incomplete and de-identified. Because a hospital cannot enhance its compatibility with the external data based on controlling variables, the use of that data may interfere with the accuracy of the final report that depicts performance and outlines recommendations for the changes that a hospital should implement to improve future outcomes.

This does not mean that a hospital should only integrate internal data as a part of its data analytics program. On the contrary, external data can and should be used given the vast quantities of relevant and insightful information it generates from the Internet of Things, Electronic Medical Records/Electronic Health Records (EMR/EHR), insurance providers, computerized physician order entry (CPOE), and clinical decision support systems. The law, administrative agencies like CMS, or even software developers of healthcare analytics, need to raise awareness about the importance of choosing external data that is compatible with the hospital's patient population, size, and intricacies of treatment. Even when our hospital from Jacksonville, Florida<sup>58</sup> turns to the Big Data to help fill in the gaps to gain a deeper insight into

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<sup>57</sup> See David Belk MD, *Hospital Financial Analysis Print Section*, TRUE COST OF HEALTH-CARE (2018), [http://truecostofhealthcare.org/hospital\\_financial\\_analysis/](http://truecostofhealthcare.org/hospital_financial_analysis/).

<sup>58</sup> See Makoviy, *supra* Part I.

the transmission of infection, it needs data that was generated with common variables during its conception – the primary condition being treated for, age, gender, concurrent diseases, and geographic area.

## VII. PROPOSED SOLUTIONS: ENHANCED FEDERAL OVERSIGHT AND ISSUANCE OF GUIDANCE MATERIALS

To help lower the risk of error that the externally generated data may produce, I present two solutions. The first solution proposes direct regulatory reform within the Social Security Act Section 1886(o), which would specify that software developers or hospitals administration may only use external data if it satisfies an enumerated set of criteria. These criteria would mandate that the external data extracted from the Big Data pool must: (i) have an identifiable source – where and under which circumstances the data was originally generated; and (ii) have a list or a key outlining predominant variables which most influenced the data’s outcomes. The drafters of the Social Security Act Section 1886(o) chose not to enumerate the requisite measures for the Value-Based Purchasing (VBP) Program.<sup>59</sup> Currently, the amendment broadly outlines parameters for such measures.<sup>60</sup> Based on the preexisting tendency to preserve ambiguity in the legislative text, my solution may face resistance for an explicit directive. If the law opts for adopting a similar set of broad parameters, but for the external data usage, the problem will prevail. Only clearly defined language with a precise data standard will ensure uniformity in the way external data is organized. Given the healthcare data’s rate of growth,<sup>61</sup> uniformity in its organization is key to sustain compliance with the VBP Program long-term. To achieve this goal,

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<sup>59</sup> See Makoviy, *supra* Part IV.

<sup>60</sup> See *id.*

<sup>61</sup> See Makoviy, *supra* Part II.

software communities across the nation will recognize the necessity to collectively begin organizing healthcare-related data into clean, identifiable, and compatible categories from the moment that data enters the Big Data pool.

The second solution proposes that the Centers for Medicare & Medicaid (CMS)<sup>62</sup> issue a series of informational and educational guidance materials, tailored to emphasize the importance of using external data that is identifiable and compatible with the hospital's agenda. In April of 2019, the Commissioner of the Food and Drug Administration (FDA) announced that the administration is working on tailoring guidance materials to help medical device developers bring artificial intelligence devices with unlocked algorithms to market.<sup>63</sup> The unlocked algorithms use machine learning to continuously learn and adapt to code modifications that the device undergoes after processing external data.<sup>64</sup> The administration recognized that the integration of external data may pose risks to patients. Consequentially, its first reactive step was to announce issuance of a comprehensive set of guidances that would outline how manufacturers can manage and control risks of the modifications that result from the input of external data. Similar to FDA, CMS should collaborate with creators of healthcare analytics to co-author guidance materials, which would specify: (i) how Big Data is generated; (ii) what risks are associated with the use of external data; and (iii) specific steps hospitals should take to maximize the benefits of external data usage, while effectuating their goals. Having CMS issue a reliable source of information may propel a movement across the healthcare community to prioritize productive sourcing of data that in turn may inspire a change on the federal level.

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<sup>62</sup> See Makoviy, *supra* Part V.

<sup>63</sup> See *Statement from FDA Commissioner Scott Gottlieb, M.D. on steps toward a new, tailored review framework for artificial intelligence-based medical devices*, (citing News & Events), U.S. FOOD & DRUG ADMINISTRATION (Apr. 2, 2019), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm635083.htm>.

<sup>64</sup> See *id.*

## VIII. CONCLUSION

The Value-Based Purchasing (VBP) Program conditions millions of dollars' worth of Medicare repayments on the quality of patient care hospitals deliver. To maximize the percentage of reimbursement, hospitals generate and submit mandatory data reports that record quality of care throughout a year. The hospital administration and software developers are keen at recognizing that the use of external data as a part of healthcare analytics can provide innovative approaches to patient care. However, the external data originates from a spectrum of sources, which are often unknown. As a result, it risks skewing the reports because it is unstructured, unidentifiable, incompatible, and incomplete. The VBP Program can withhold up to 90% of the total repayment per hospital if there is a recorded decrease in the quality of care.<sup>65</sup> The VBP Program does not investigate the accuracy of the reports. Rather, it is the hospital's responsibility to ensure the accuracy of the data in its own reports. Because the generation of reliable data is essential to sustaining the entity's financial stability and fulfilling the purpose of the VBP Program – enhanced patient quality at a lower medical cost, a change must occur. The need to minimize the risk of error during data production highlights the need for legal action to mitigate the risks associated with the delivery of misleading reports. Such legal action at a minimum would issue a series of guidances educating healthcare providers about the risks associated with external data use, and at best institute an amendment codifying a standard, external data must meet in order to qualify for use in the healthcare analytics systems.

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<sup>65</sup> See Tingyin T. Chee et al., *Current State of Value-Based Purchasing Programs*, 133(22) JMIR MHEALTH UHEALTH 1 (2017).