Risk Managing Population Health and Big Data Use

Healthcare is abuzz with population health and “big data.” Hospitals, clinically integrated networks, ACOs, patient centered medical homes and more all speak in terms of data analytics applied to population health and big data.

But just what is “population health?” And what is “big data?” What does it mean to delivery of healthcare services? What does it mean to the individual patient? And, what are the risk management exposures that need to be addressed when generating and using population health data?

The answer to these questions helps to set the context for practical risk control in generating and in using population health data.

Population Health and Big Data.

Although there are various definitions for population health, the one used by CMS is pertinent in today’s value-based healthcare economy. CMS defines population health as

“the health outcomes of a group of individuals, including the distribution of such outcomes within the group.”¹

In the CMS approach to population health the emphasis is on both outcome and process measures. The former is supposed to demonstrate the health of either a specific population or community. The latter looks at

“the primary prevention of disease or screening for early detection of disease that is unrelated to a current or prior condition.”²
Big Data, as the name suggests, requires accessibility to copious amounts of healthcare information. The data may be clinical in nature. It may be process or outcome information. It may also include financial information. Putting it all together, there is a wealth of information that can be used to drive healthcare delivery policy and services.

Population health relies to a good extent on big data. Narrow or small data samples can lead to inaccurate inferences and wrong choice-making. Hence, population health and big data need to be considered together in terms of possible risk factors. To quote the oft-used phrase from the computer sciences, “garbage [data] in equals garbage [data] out.”

**The Legal – Regulatory Context for Federal Population Health Initiatives.**

The CMS initiative is premised on a variety of federal laws, regulations, and public policy. The legislative foundation for recent population health initiatives can be seen in such laws as the American Recovery and Reinvestment Act of 2009 (ARRA)\(^3\), the Affordable Care Act of 2010 (ACA)\(^4\), The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act)\(^5\), and the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)\(^6\). Based on this enabling legislation CMS has either proposed\(^7\) or promulgated a full range of regulations.\(^8\)

The shift to the “Physician Quality Reporting System” (PQRS)\(^9\), the Merit-Based Incentive Payment System (MIPS)\(^10\) and the emphasis on patient-reported outcome measures (PROMS)\(^11\) are also part of the groundwork for population health. Taking into consideration CMS innovations programs (CMMI)\(^12\), the comparative effectiveness research through the auspices of the Patient-Centered Outcomes Research Institute (PCORI)\(^13\), the changes found in the Affordable Care Act, including the Medicare Shared Savings Program and accountable care organizations (ACOs)\(^14\), and patient-centered medical homes (PCMH)\(^15\), one can see a complex mosaic of quality measures intended to make the most of healthcare dollars and resources for Medicare and Medicaid beneficiaries and children enrolled in the CHIPS\(^16\) program.

Quality is taken one step further in this latest rendition of quality measures policy, with the clear emphasis on both process and outcome measures. Given the looming growth in the number of Medicare beneficiaries among the “baby-
boomer” population, it is understandable that CMS wants to eliminate needless tests and treatments and focus on what will result in the greatest value for the service population.

What is Good for CMS May Also Be Reflected in the Public Health Insurance Sector.

Private payers are not sitting idly as CMS rolls out its value-based system. Indeed, the private payer side has its own data resources from which to develop its own population health algorithms. The private sector side has long used its data to define or substantiate why certain tests, treatments or drugs will or will not be covered. In other words, in designing a health insurance program or plan the private sector asks basically the same questions: given the service population, what are the health outcomes? What can be improved? What services should be eliminated?

Risk Exposures with Population Health.

Population health is not without risk exposures. Indeed, the risk exposures impact not only federal population health initiatives, but also, those programs found in the private sector. The risks involve more than reimbursement levels, and encompass what preventive and clinical services are offered. As such, population health based decision-making could have a negative effect on delivery of screening tests, treatments, and the programs that administer such activities.

Indeed, what was one day a robust, preventive service program may see funding evaporate with a bureaucratic determination based on population health outcome data. The rationale is that the cost of doing business cannot be justified given the “n,” the number of beneficiaries using the service or the outcomes achieved through the program. Healthcare jobs will be lost and patient-centered resources eliminated. Patients may be told that while the service is still funded, it will no longer be available in that community. A lack of transportation or long travel time can leave the end user in a preventive service desert.

There are other risk exposures to consider. These include the following:

- Inaccurate data leading to imprudent decision-making.
- Ignoring population data to the detriment of the service population.
• Inaccurate calculations based on population health outcomes or process measures resulting in inaccurate value-based payments.
• Inconsistent methodologies used to calculate outcomes or process measures causing inappropriate changes in services and deliverables.
• Changing analytical methods to achieve certain outcome or process data results.
• Lack of statistic precision resulting in drawing the wrong inferences from data.

Three other risk exposures merit specific discussion. First, is the risk of fiduciary breach. Relying on inferences drawn from population health data, the governing body of a non-profit healthcare organization may make a major decision on opening, expanding or closing a service line. If the data is flawed, or the sample size is too small on which to base the determination, the result could be an allegation of a fiduciary breach. How? The decision is seen as withdrawing from the non-profit healthcare organization’s mandate or stated charitable service program. If the data was specious or inaccurate, and, at the same time, no one examined the data carefully, it could be seen as a failure on the part of the stewards of the organization to act in a fiduciary manner.

A second related risk is taking the population data at face value. Like any other data it must be evaluated carefully. Decision-making relies on accurate, timely data. Statistical discernment is needed. In practice, statistical discernment means asking the right questions, such as:

• When was the data collected? Is it still current to support decision-making?
• Has the data been reviewed for accuracy? Has the data been put through its paces with falsification testing?¹⁷
• Is the data correlated with what is termed observational methods to essentially “stress test” the information?¹⁸

Why is this important? Think about the use of population data to help justify the build-out of a satellite service for a healthcare system. Bonds are considered the primary way to fund the project. When the prospective bondholder completes a “due diligence” of the data assumptions, any findings of stale, inaccurate or untested data can easily thwart access to such funding.

A third risk involves patients. In the purest sense of population health information, the focus is on outcomes and process measures, driving the greatest gains for a
large segment of the service sector. In taking this approach, resources are marshaled for an application to those who are perceived to need it.

Think about population health measures in the context of preventive services. The US Preventive Services Task Force\(^\text{19}\) develops guidelines on who should receive screening services for such health concerns as prostate cancer, osteoporosis, breast cancer, etc. If population health data drives the process, a portion of the prospective service sector will not receive a recommendation for screening tests. The argument is that for this group such testing is not medically necessary based on the outcome measures data.

Outcome measures should not be applied in isolation. There must still be patient evaluation, taking into consideration individual risk factors. Thus a population-health based preventive screening guide may discourage any breast cancer screening for anyone under the age of 40. However, the individualized observational information is that a 36-year-old female has a strong family history of breast cancer among her mother, aunt, and maternal grandmother.

A health plan may initially decline to pay for the screening exam. Such a decision may be reversed quickly with the input of individualized, observational information furnished by the care provider.

In practical terms, care providers should be ready to challenge the application of population health preventive “guidelines.” The needs of an individual patient must be considered – not just what population health data seems to suggest is warranted.

**Population Health, Big Data and Enterprise Risk Management.**

Population health efforts are here to stay. With access to a pool of big data, it has become part of the fabric of healthcare public policy. It will persist as a driver in terms of service delivery and reimbursement.

As discussed here, acceptance of, and reliance on, population health based policy poses risks for government, private payers, healthcare organizations, healthcare professionals and patients. In many ways, however, the risks associated with population health initiatives are amenable to enterprise risk management (ERM).
Some may question such an assertion. Consider the domains of risk brought into sharp focus by population health: human capital, operations, technology, hazards, legal-regulatory requirements, strategic planning, and financial issues.

Consider too, that healthcare enterprise risk management is intrinsic to the organization. It shapes business decision-making, using reliable information or data to drive prudent choice-making while reducing process variability and uncertainty in the delivery of healthcare services. By eliminating wasteful, redundant processes, funds can be saved and leveraged for expansion of services while enhancing patient care.

Population health and ERM are not only compatible, but complimentary. The principles and practices of ERM may well be the way to avoid many of the risk factors associated with population health.

Strategies for Risk Managing Population Health and Big Data Use.

The credibility of population health efforts depends on accurate, timely and reliable data. The failure to follow consistent data collection, analytic, and application methods can result in needless risk exposures. Strategies for this purpose include the following:

1. **Complete a Risk Inventory on the Collection and Analysis of Population and Big Data.**
   Examine closely the sources used from which information is gathered and used to draw conclusions on population health. Look for such risk issues as timeliness, accuracy, and completeness of the information. Do the same for so-called “Big Data” resources used in business analytics.

2. **Evaluate the Information Collected.**
   Assess the results of the risk inventory. Determine if the data contains vulnerabilities or could lead to specious inferences or conclusions that would otherwise form the basis for strategic planning or business decision-making by the healthcare organization.

3. **Establish an ERM-Style Approach for Data Analysis, Use, and Application.**
Make recommendations to senior leadership and the governing body for an enterprise risk management method for collecting, assessing, and applying information obtained for purposes of population health. Emphasize the importance of consistent, accuracy, and timely data aggregation and use. Stress the importance of using the data across those domains of risk that are apt to be affected by population health and big data.

4. **Address Vulnerabilities in External Data Collection.**
   Work with key stakeholders to eliminate or mitigate weaknesses in information drawn from outside resources for population health and big data. Focus on inconsistent data set size as well as variations in data collection methods, timeliness, and accuracy. Discuss with legal counsel contract mechanisms that can be used to reduce the risk of data vulnerabilities, such as data source offering information from an unapproved third party. Consider including in big data contracts a clause for the right of first refusal to accept information from a successor organization absent careful vetting and due diligence of that new entity.

5. **Educate: Evaluate Population Health and Big Data Base Guidelines.**
   Encourage focused education for the governing body and leadership team on how to assess and use population health and big data details in business decision-making. Offer a similar program for clinical leadership responsible for developing policy, procedure and protocols for patient care.

6. **Have in Place a Pathway for Addressing Population Health Data Outliers.**
   Be ready to examine, explain and act on data that points to unexpected or variations. Use a consistent methodology to examine and act on what is considered abhorrent or outlier information, including when appropriate, a review of business-decisions and clinical protocols. Document the process for review and action.

7. **Documentation: Close the Loop on Substantiating Use of Population Health Data.**
   Recognizing the various uses of population health and big data, reinforce the importance of documenting the rationale for choices made based on such information. Emphasize the importance of showing deliberate
decision-making premised on such information that is consistent with the mission, vision, values and enterprise risk management approach of the organization. Explain why such choices were made and why other options were not considered acceptable for the organization and the service population.

Conclusion.

Population health and access to “big data” is part of the transformation of contemporary healthcare systems. Like any other type of data, the information needs to be carefully analyzed prior to using it as the basis for critical decisions.

Using an enterprise risk management approach, much can be done to control or manage exposures associated with population health efforts. Examining relevant risk domains and analyzing possible exposures, prudent questions can be asked about the reliability of population health data and recommendations can be made to manage possible problem areas. The governing body and leadership of an organization can help establish a process for risk managing population health and big data use that supports the mission, vision and values of the enterprise.

If you would like assistance in developing enterprise risk management based policies and procedures, please contact The Rozovsky Group.

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