EXPLORING THE RISKS AND IMPLICATIONS OF CMS FINAL RULE 0057: INTEROPERABILITY AND PRIOR AUTHORIZATION

Implementing operational efficiency, meeting regulatory requirements, and improving the overall member and provider experience.

EXECUTIVE SUMMARY

The Centers for Medicare & Medicaid Services (CMS) recently published the Final Rule 0057 in January 2024, which presents some significant regulatory requirements in the interest of improving interoperability and streamlining prior authorization processes. This rule aims to give patients better access to their health information, ease administrative burdens, and increase transparency in healthcare. However, it poses many risks—technical, operational, financial, and legal—once implemented. This Trexin Insight Paper (TIP) evaluates these risks and their implications for healthcare payers, providers, and patients.

INTRODUCTION

Interoperability is the bedrock of modernizing the healthcare system, enabling seamless exchange of data between stakeholders and, most importantly, better outcomes for patients. Prior authorization (PA)—intended to ensure proper and cost-effective care—has long been criticized for its delays and inefficiencies in the process. The CMS Final Rule 0057 addressed these concerns by mandating the use of standardized, Fast Healthcare Interoperability Resources (FHIR) a healthcare data standard that includes an application programming interface (API) for exchanging electronic health records (EHR) FHIR-based APIs and encouraging transparency. While this rule has flung open the doors very wide for advancement, it also opens up complexities that demand careful consideration.

KEY PROVISIONS OF CMS FINAL RULE 0057

1. Adoption and standardization of FHIR-based APIs to seamlessly share data between payers, providers, and patients.
2. Automation of the prior authorization workflows to achieve efficiency and reduction in processing delays and administrative overheads.
3. Empowering patients with their healthcare information and data in a timely manner.
4. Integrating the prior authorization process between provider and payers using providers' EHR systems.
5. Payer to be transparent and report out prior authorization metrics of response times and approvals.

RISKS ASSOCIATED WITH CMS FINAL RULE 0057

1. **Technical Risks**
   - The new FHIR-based APIs may not be compatible with legacy applications, which can lead to integration challenges.
   - The increased exchange of data among providers and payers will heighten the data security risks associated with breaches and other misuses.
   - Higher volumes of data will burden existing infrastructure, which can lead to disruptions of applications and systems.

2. **Operational Risks**
    - The new APIs and workflows will lead to disruptions and temporarily destabilize operations.
    - Having implemented new workflows and processes, the training of the staff needs to be addressed.
    - Ensuring all the stakeholders, including providers, payers, vendors, EMR/EHR vendors, and other technology providers, are coordinated and aligned with CMS's mandate.

3. **Financial Risks**
    - The development of new APIs and upgrading the infrastructure will lead to high implementation costs.
    - Non-compliance will result in compliance penalties and reputational damage.
    - Due to budgetary constraints, human and technology/infrastructure resources might not be allocated, especially in smaller organizations.

4. **Regulatory Risks**
    - Due to the complexity of CMS rules, there will be ambiguity in interpretation, resulting in inconsistent application of the mandate.
    - Patient care will be jeopardized due to incorrect or delayed PA processing, resulting in legal challenges.

IMPLICATIONS OF CMS FINAL RULE 0057

1. **For Healthcare Payers**
    - The implementation of APIs and a streamlined PA process will bring about enhanced efficiency, reducing administrative costs.
    - Enforcement of the transparency requirements will increase scrutiny of operational processes, leading to greater accountability.

2. **For Providers**
    - Enhanced and improved PA processes and workflows can reduce the delay in care delivery.
    - Providers will encounter adoption challenges as they are transitioning to integrate systems and will require significant adjustment.

3. **For Patients**
    - This will allow patients more access to health information, leading to empowered decision-making and enabling them to make informed choices.
    - The patients will need to be more vigilant regarding their health information as the data is being exchanged, which will potentially raise the risks of confidentiality.

STRATEGIES TO MITIGATE THE RISKS

CMS Final Rule 0057 has brought transformative changes in how the stakeholders in the healthcare system manage data exchange and prior authorizations. The opportunities are huge, but risks require bold and forward-looking strategies. Here are some noteworthy approaches tied directly to the rule provisions:

1. **AI-Driven Security**
    This forces organizations to use FHIR APIs because of CMS Final Rule 0057, making security a must for survival. What this simply means is that mere adherence to set rules by stakeholders is not enough. Imagine security rules powered by AI set up to predict problems before they occur. Establish a system where every API

transaction is validated in real time by using advanced machine learning models that ensure your commitment to patient data privacy is significantly more steadfast than the rules require.

2. **Phased Implementation**
   Instead of a phased approach, organizations should seek "micro-wins." For example, they can initiate pilots of the most difficult aspects of integration with FHIR API in high-priority areas like oncology or cardiology, where the stakes for efficient prior authorizations are especially high. These focused implementations allow for proof-of-concept successes, which can be celebrated and then built upon to sustain the momentum needed to meet CMS's aggressive timelines without losing interest from stakeholders.

3. **Forging Partnerships**
   In order to comply with Final Rule 0057 and innovate simultaneously, healthcare organizations need to partner with each other (payers, providers, and vendors) and also establish partnerships that extend beyond the industry to include technology disruptors like blockchain companies or cloud-native startups. Such alliances may redefine how prior authorization data is validated and shared using decentralized systems for a level of transparency and security that has never been seen.

4. **Training**
   Interoperability in real-time is complicated; it's more than just standard training. Imagine gamifying the adoption process, for example, providing "compliance points" for completing FHIR-based tasks or streamlining prior authorization workflows. Tie these rewards to company goals and build a culture where staff are not only trained but eager to follow CMS 0057's mandate.

5. **Agility**
   CMS 0057 brings in accountability and transparency, demanding real-time reporting. Put in place agile systems that go beyond the tracking of numbers to deliver useful information, such as automated alerts in case approvals for prior authorizations fall below set limits, triggering quick reviews and changes in the process. Use the public reporting rules to demonstrate how your organization is responsive and committed to patient care.

6. **Embrace the Change**
   CMS 0057's rule on transparency should not be feared; it should be embraced. Those healthcare organizations which are transparent with their performance measures and engage with patients via easy-to-read dashboards will be the leaders of this industry. Transparency breeds trust and makes payers and providers stand out, particularly in a competitive market.

CONCLUSION

CMS Final Rule 0057 was released in January 2024 which was built on the technological foundation of the May 2020 CMS Interoperability and Patient Access Final Rule (85 FR 25510) under the previous Trump administration. As the 2nd term of Trump's administration is poised to take over, it will be interesting to observe how these policies will be impacted.

CMS Final Rule 0057 goes beyond mere regulation; it calls for a revolution. Wholeheartedly embracing of such bold and ambitious strategies by the organizations will transform risks into opportunities. In this new arena, victory will belong solely to those who rise to the challenge—those who innovate, lead, and inspire—not to those who merely comply.

As the payers and providers embark on the path to implement the CMS Final Rule 0057, which is designed to drive health interoperability and simplify prior authorization for the great benefit of all stakeholders, they also face equally

great risks. In such a scenario, it becomes very important that all the stakeholders take a proactive approach, working closely with each other to overcome these challenges by using technology, generative AI, policy, and education. Strategic management of the risks identified above allows healthcare organizations to progress toward achieving the twin objectives of efficiency and patient-centered care.

REFERENCES

CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F)
https://www.cms.gov/priorities/key-initiatives/burden-reduction/interoperability/policies-and-regulations/cms-interoperability-and-prior-authorization-final-rule-cms-0057-f

Prior Authorization Implementation Guide Home Page
https://build.fhir.org/ig/HL7/davinci-pas/

Da Vinci Payer Data Exchange
https://build.fhir.org/ig/HL7/davinci-epdx/

This TIP is designed to provide healthcare stakeholders with a comprehensive understanding of the risks and implications of CMS Final Rule 0057, serving as a guide for informed decision-making and successful implementation.

This TIP was written by Asim Jeelani. Asim welcomes comments and discussion on this topic and can be reached at asim.jeelani@trexin.com.