July 21, 2020

- **While all eyes are on the Trump Administration's response to the COVID-19 pandemic, the President's attempts to roll back provisions of the Patient Protection and Affordable Care Act ("PPACA") still loom large.**
  - On January 20, 2017, the President issued Executive Order 13765, "Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal," prompting executive departments and agencies to "waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of [PPACA] that would impose a fiscal burden on any State or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications."
  - In a proposed rule published on July 15, 2020, the Departments of the Treasury, Labor and Health and Human Services (the "Departments") set their sights on grandfathered group health plans and grandfathered group health insurance coverage (collectively, "Grandfathered Plans"). If finalized in its current form, beneficiaries could face an increase in out-of-pocket costs.
  - PPACA provides that Grandfathered Plans are subject to some, but not all, provisions of PPACA. If Grandfathered Plans make certain changes to their health plans, however, they lose their grandfathered status.
  - The proposed rule, if implemented, would allow certain Grandfathered Plans to make changes to their cost-sharing requirements without losing grandfathered status. Although such changes could result in increased out-of-pocket costs for beneficiaries, the proposed rule would provide greater flexibility for certain Grandfathered Plans. For example, Grandfathered Plans that are high deductible health plans ("HDHPs") could make changes to their fixed-amount cost-sharing requirements if such changes are necessary to maintain their status as HDHPs under Section 223(c)(2) of the Internal Revenue Code.
  - Citing a 2019 Kaiser Family Foundation survey on the prevalence of Grandfathered Plans, the Departments provide that they do not expect a significant impact on the number of grandfathered group health plans as a result of the proposed rule. The Departments, however, provide scant analysis of the proposed rule's potential impact on out-of-pocket costs to beneficiaries who depend upon such health plans and whether Grandfathered Plans that are HDHPs will actually change their fixed-amount cost-sharing requirements.
  - **Key Takeaway**: Although concerns surrounding the COVID-19 crisis remain at the forefront, health care industry stakeholders must continue to pay careful attention to the evolving regulatory terrain surrounding PPACA, especially when the need to access quality, affordable health care is at an all-time high.
- **COVID-19 has the potential to have lasting effects on hospital emergency department utilization.**
  - A recent report from TransUnion Healthcare found that while hospital inpatient and outpatient volumes were back up to over 90% of pre-COVID levels, emergency department ("ED") visits were still lagging behind, having reached only 75% of pre-COVID levels.
  - The disparity was even more pronounced among children, where ED visits were at just 41% of pre-COVID levels. This could be attributable to children having more lower acuity issues that

can be appropriately treated in other settings. The report also noted that ED visits for low-acuity issues were returning slower than those for high-acuity issues.

- There are legitimate concerns around deferrals of patient care due to COVID-19, but the pandemic has also forced many patients to adapt and seek appropriate care through alternatives such as telehealth, urgent care or primary care clinics. These learned adaptations are likely to continue beyond COVID-19–particularly as patients become more aware of the significantly higher cost of ED visits.
- This trend could be a positive development towards more cost-effective care and lowering overall costs for employers and patients. However, hospitals need to be prepared to deal with the financial implications of lower ED volumes and should be proactively pursuing opportunities to expand their ability to provide care through lower cost alternatives.
- **Key takeaway**: Patients are learning to adapt their health care utilization in positive ways as a result of COVID-19 and this could have lasting effects on ED volumes that hospitals need to be proactively addressing by adapting their own models for care delivery.

- **Amendments to the federal regulations protecting substance use disorder ("SUD") records at 42 C.F.R. Part 2 ("Part 2") are effective August 14, 2020, and further changes are coming.**
  - A new final rule issued by the Department of Health and Human Services' ("HHS") Substance Abuse and Mental Health Services Administration ("SAMHSA") modifies the existing federal regulations for SUD records. The new rule adopts with limited modifications SAMHSA's August 2019 proposed rule and is designed to align the Part 2 regulations with advancements in the health care delivery system and facilitate coordinated care, while at the same time ensuring appropriate privacy protections for individuals seeking SUD treatment.
  - Providers subject to Part 2 must comply with the updated regulations as of August 14, 2020. Notably, however, the updated regulations do not implement any of the statutory amendments to the Part 2 authorizing statute, 42 U.S.C. § 290dd-2, effected by Section 3221 of the CARES Act. The CARES Act amendments are significant, changing or adding
    - definitions;
    - antidiscrimination provisions;
    - breach notification requirements;
    - requirements for patient consent;
    - standards for the use of records in legal proceedings;
    - a requirement to issue a notice of privacy practices;
    - provisions authorizing the disclosure of de-identified SUD information to public health authorities; and
    - penalties for violations.
  - Although the CARES Act requires HHS to amend the Part 2 regulations to implement these statutory changes, the CARES Act provides that the Part 2 related provisions will not take effect until March 27, 2021. In the final rule published last week, HHS indicated that it intends to issue a notice of proposed rulemaking within the next 12 months to address the CARES Act requirements. Providers should expect the proposed rule to offer even greater flexibility for

patients and health care providers to share SUD records than is presently allowed, and to more closely align Part 2 confidentiality standards with HIPAA.

- While HHS has delayed the effective date and/or enforcement of other federal regulations due to the COVID-19 pandemic, there has been no indication that SAMSHA intends to delay the effective date of the final rule updating the Part 2 regulations.
- **Key Takeaway**: The final rule implementing amendments to Part 2 is intended to provide transitional regulations until regulations implementing Section 3221 of the CARES Act are promulgated and finalized.

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