



Successful Regulatory Relationships Post-COVID-19 with Sponsors and FDRs



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Disclaimer: Views expressed by the speakers in this presentation are their own and not necessarily those endorsed by either PPHP or Prime Therapeutics

COVID-19 Phenomena

The COVID-19 Pandemic will likely be referred to as a Black Swan Event after all is said and done.

“A **black swan** is an unpredictable **event** that is beyond what is normally expected of a situation and has potentially severe consequences. **Black swan events** are characterized by their extreme rarity, severe impact, and the widespread insistence they were obvious in hindsight.”

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COVID and Regulatory Landscape

Pre-COVID, there were “knowns”

- This conference was going to be held live and in-person where it first started a decade or so ago- in Arizona- yet here we are meeting virtually
- CMS would be holding its respective Spring and Fall Audit Conferences at 7500 Security Blvd, with webinar capability, of course
- CMS would be conducting approximately 30+ Program Audits as part of its 3-year cycle in addition to a myriad of other audits (e.g., 1/3 Financial, DVA, TMP, etc.)
- Some of us in Compliance may have even scheduled onsite visits to meet with respective Plan Managers at their Regional Office

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Successful Regulatory Relationships are Crucial in Times of Crises

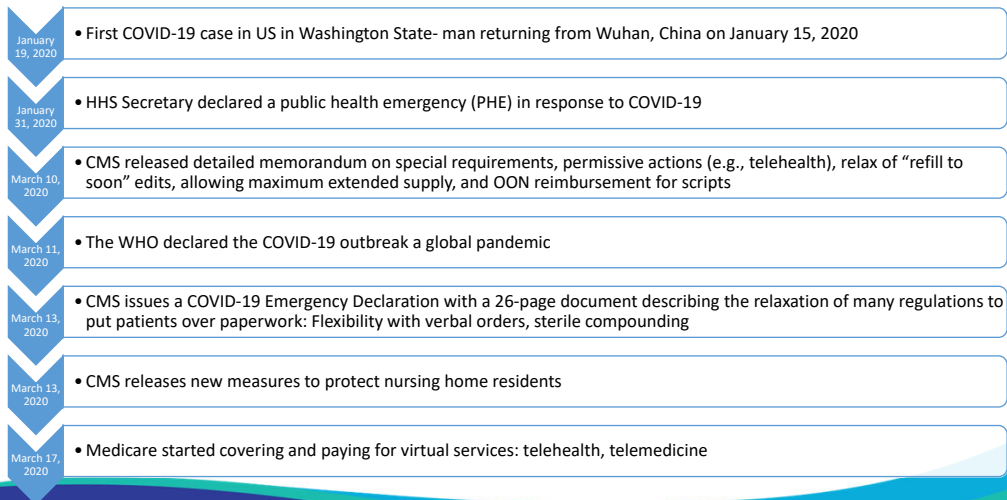
- Pandemic has presented enormous health care challenges
- The time has never been more crucial for Plans to be in sync with Regulators to assure healthcare access for members/beneficiaries



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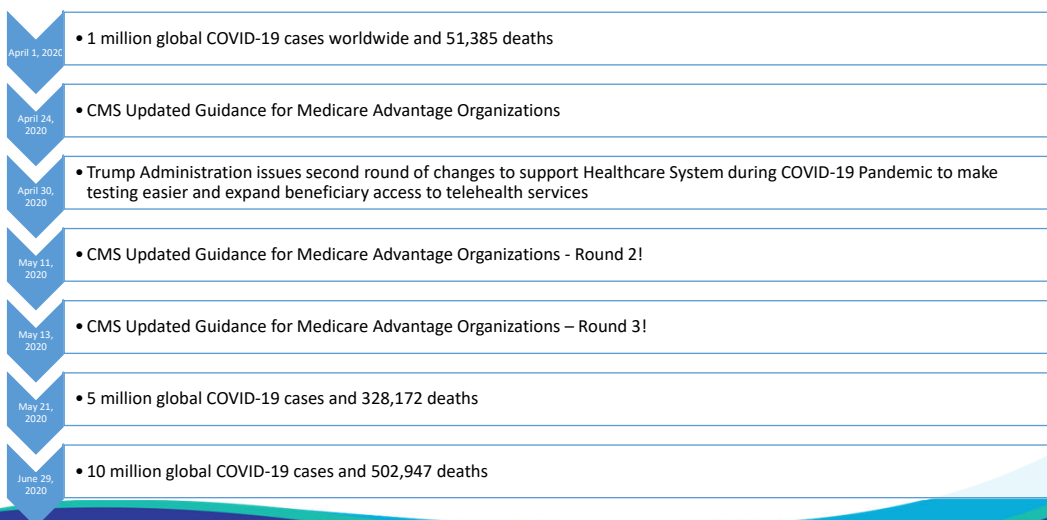
Event Timeline – Highlights



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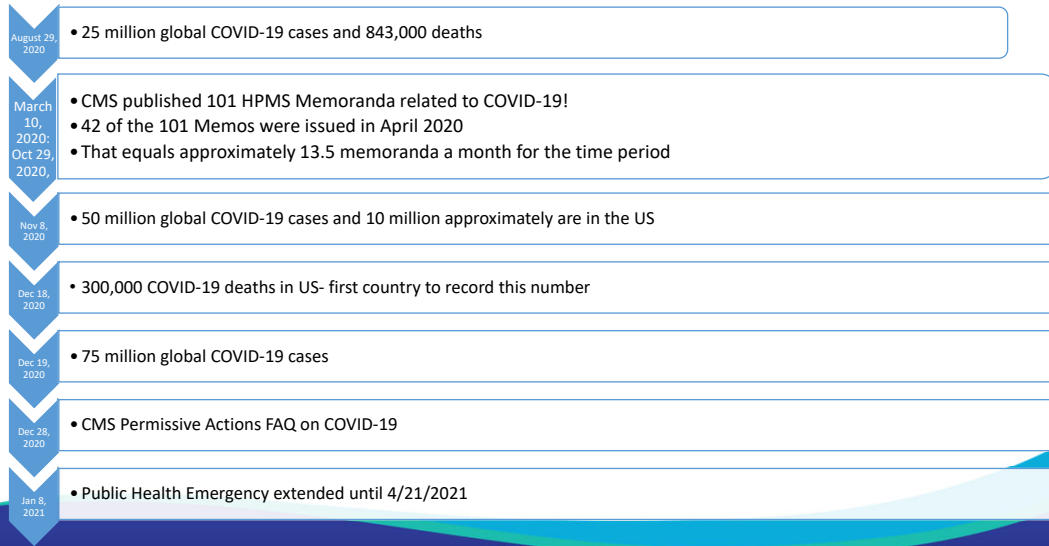
Event Timeline (Cont'd)



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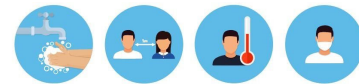
Event Timeline (Cont'd)



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Notable COVID Related Regulatory/Administrative Challenges from 2020

1. Delayed Audits and Audits Overload
2. New regulatory trends- telemedicine/telehealth
3. Relaxation of rules for COVID-19, co-payments
4. States of Emergency/Upheaval with Beneficiaries/Job Market Changes
5. Drastic reduction in face-to-face meetings- sales, regulators, colleagues, industry conferences, etc.
6. "New" technologies: ZOOM, GTM, WebEx, TEAMS- but what about privacy?
7. Nursing Facilities- COVID-19 I-SNP Impact
8. Political Pressures from an election year



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Best Practice: Be Ready for Change

New Regulations: Telemedicine/Telehealth

- MA Plans have been able to provide telehealth services as a supplemental benefit since 2013
- MA Plans have been wanting to expand use of Telemedicine to address access issues and expand coverage. Strong member data supporting use of Telemedicine based on commercial plans practice.
- Due to the public health emergency, starting plan year 2020, MA plans were allowed to provide additional telehealth benefits not previously allowed to enrollees as basic benefits
- CMS updated network adequacy requirements and allowed visits conducted via telehealth to count towards risk adjustment

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Be Ready for Change

New regulations- Telemedicine/Telehealth

- Congressional action to address the COVID-19 pandemic gave agencies authority to provide funding and change policy which resulted in telehealth expansion
- CMS has allowed MAO's to offer midyear benefit enhancements for the length of the COVID-19 Emergency
- Quickly adapt to using with Medicare population
- Expectations set for members/beneficiaries – will CMS permanently enact, or will it be pulled back?
- Regulatory clarity concerns/Opportunity for input

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Best Practice: Rethink Audit Planning

COVID has Caused Delayed Audits and Audits Overload

- CMS suspended or “re-prioritized Program Audits, 1/3 Financial Audits, DVA, HHS-RADV Audits, PACE, etc. due to the Public Health Emergency Declaration- March 30, 2020
- Apprehension as to which set of Program Audit protocols, Sponsors needed to prepare for- proceed with the 2020 Audit Protocols approved mid-year? Or work with stakeholders to prepare them for 2021 Protocols set?
- Majority of Sponsors did not have the resources to prepare for both sets, so they had to make a choice.
- CMS restarts 2020 Audit Season with engagement letters using 2020 Protocols- July 27, 2020
- CMS resuming audits through September! - December 23, 2020

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Best Practice: Rethink Audit Planning

- Public Health Emergency Declaration renewed January 8, 2021 for 90 days.
- CMS continuing use of 2020 Protocols for 2021 Program Audits due to pending OMB approval- October 29, 2020 HPMS Memorandum
- 2021 PACE and Medicare Parts C & D Program Audits cycle to resume March 2021, but with new administration and CMS leadership, and now engagement letters will be sent out through September 2021 – December 23, 2020 HPMS Memorandum
- Contract Year 2021 COVID-19 Permissive Actions FAQ on Enforcement Discretion Policies- December 28, 2020 HPMS Memorandum

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Best Practice: Audit Readiness

- Readiness: Continue your **readiness** activities. If you had Mock Audits planned for this year, and are still logistically able engage in those reviews, do so.
- Mock Audit Planning: If you were expecting a program audit this year, and didn't plan any **Mock Audit** activities, consider working in additional reviews to maintain your organizational readiness if able.
- There are external consultants in the industry with a high degree of flexibility who can help make Mock Audit activities happen in this temporary reality where everyone is working remotely.

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Best Practice: Adaptability

- Remoteness of workforce – Enforce compliance, onboarding remotely
- Privacy/HIPAA Compliance
 - Lock screen and printing materials at home, families in rooms, Work from home safety measures
- Data Security/FWA
- How quick can your Plan adapt to new regulatory changes?
- Innovation/Advocacy ideas to CMS based on commercial models
- Change in Administration – what changes will be planned/rolled back?
- How to work with members who have grown accustomed to new benefits like telehealth?

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Best Practices: FDR Management

- Downstream impacts to FDR's and Supply Chains
 - Interruptions in supply chains may impact your ability to comply
 - Privacy breaches - Malware
 - Financial security of FDRs/Workforce reductions
 - Educate Vendors about Health Care Compliance



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Best Practices: Relationship Opportunities

- **Relationship** skills paramount – make things easier for your regulator, more crucial than ever to be a partner, anticipate your regulator's needs
- Developing a **regulatory communication strategy** in a more virtual world with quick actions and fast deployment capabilities
- Compliance **Continuity Planning** – be ahead of the next crisis; demonstrate competency
 - Understand what is around the corner
 - Anticipate emergencies and how your organization will respond

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Summary

- Expect the Unexpected – what are other potential Black Swans and how will your organization deal with them?
- Be Nimble and Agile
- Rethink Standard Practices
- Open, Strategic and Timely Communication Crucial
- Relationships are critical and always need to be strengthened and nurtured

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Questions, Comments, Thoughts?

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