Predictions for 2021

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AS 2020 ENDS, MANY OF US ARE LIKELY THINKING, "Good riddance!" 2021 is bound to be an improvement upon 2020. Specific to the world of pharmacy, we have a few predictions for 2021.

PREDICTIONS 1 AND 2: (1) Vaccine(s) will be approved and distributed for prevention of COVID-19, the disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2); (2) Pharmacists will play a major role in its administration.

We could not write about predictions for 2021 without addressing the COVID-19 vaccine candidates. With the expected approval of a vaccine for COVID-19, the focus is turning to the distribution and reimbursement of the largest mass vaccination in recent history. Historically, the CDC (Centers for Disease Control and Prevention) has overseen the processing, distribution, and reimbursement for mass vaccine efforts. The CDC previously negotiated agreements with large pharmacy chains and set the amount of the provider administration fee through provider participation requirements. CMS (Centers for Medicare & Medicaid Services) may also aid in setting administration fees for government-sponsored plans.

To ensure uptake of the COVID-19 vaccine, CMS may evaluate additional Medicare options, such as implementing the "significant cost threshold" provision. Under the significant cost threshold provision, CMS can pay for certain high-cost new Medicare benefits through fee-for-service (FFS) Medicare. Payments may continue until the costs for the new benefits are included in the Medicare Advantage (MA) payment benchmarks. Vaccine administration fees would be billed as FFS claims for both FFS and MA patients, resulting in initial cost relief for Medicare Advantage plans. While no official guidance has been published to date, these actions are expected in 2021.

The Coronavirus Aid, Relief, and Economic Security (CARES) Act of 2020 requires that the COVID-19 vaccine be provided at no cost to insured patients. Commercial plans will have to cover these costs. Uninsured patients would be responsible for paying the administration fees directly, or may need to seek the vaccine free of charge at a county health office or similar entity. Depending on the cost, this could be a deterrent for some patients and hinder immunization efforts, leading to undesirable vaccination rates across the country.

Additional regulatory issues remain for many COVID therapies. Throughout the COVID-19 pandemic, the FDA's (Food and Drug Administration's) emergency use authorization (EUA) authority has been leveraged for multiple products, including remdesivir, COVID-19 tests, protective equipment, and more. Under the EUA, the FDA is not expediting the full regulatory approval process but permitting "emergency use" to mitigate a national emergency as defined by the act. Remdesivir was initially authorized under the act to be used for COVID-19 and only recently received full FDA approval for this indication. Medicare is not authorized to provide coverage for products authorized under an EUA, while the CARES Act provision references "licensed" products. An EUA would most likely mean the full FDA approval pathway has been circumvented, which may or may not constitute a "licensed" product. The FDA may consider other options, including "expanded access," also known as "compassionate use." This would allow wider vaccine access to patients outside of clinical trials, prior to full FDA approval. As of early November, the FDA had not announced or published its selected option for the COVID-19 vaccination efforts and may be considering options not presented here. All these issues will need to be resolved and addressed for a successful nationwide vaccination effort.

Beyond these issues, pharmacists will need to be ready to step up and lead efforts for vaccine administration. States are already working to prepare for this participation. For example, the Pennsylvania Pharmacists Association provided an update on Oct. 29, 2020 (see the box at right), about steps that pharmacies should complete to prepare for administration of COVID-19 vaccinations, acknowledging that information is changing daily. We expect that other states will have similar requirements for pharmacist administration of COVID-19 vaccines.

PREDICTION 3: More definitive 340B guidance will be announced.

In September 2020, several brand pharmaceutical manufacturers

took aggressive steps to reduce their risk of paying duplicate discounts in the 340B drug program. The 340B program provides covered entities with sizeable discounts on pharmaceuticals, and drug manufacturers are required to participate in the 340B program as an OBRA '90 Medicaid rebate requirement.

Two manufacturers noted that they would stop providing hospitals with 340B discounts if the hospital, as a covered entity, was ordering product for a contract pharmacy versus dispensing the product at an in-house pharmacy. Both manufacturers will continue to provide discount pricing to covered entities and their child sites outside the contract pharmacy arrangement. For covered entities that do not have an on-site dispensing pharmacy, the manufacturers noted that covered entities can arrange for a single contract pharmacy of their choosing to receive 340B pricing on behalf of the covered entity, which may require applying for an exception. The covered entity would not, however, be able to purchase product for an unlimited number of contract pharmacies. These new tactics are challenging the proliferation of contract pharmacy arrangements.

In response to these manufacturer actions, Apexus, the 340B Prime Vendor Program, published a sample form for covered entities to report instances where covered outpatient drugs are not available at a 340B ceiling price or are charged at the incorrect 340B ceiling price. The form specifically asks if the issue reported is limited to a contract pharmacy purchase, which could help target where availability or pricing issues are specifically related to these recent manufacturer changes. Completed forms are to be emailed to the HRSA (Health Resources and Services Administration). Based on the availability of this form and its uptake and use by covered entities, the HRSA will begin to quantify the extent and impact of manufacturers' refusal to provide 340B pricing to all contract pharmacies.

As this back and forth continues, we expect that this will either push the HRSA to reform the 340B program or result in more definitive guidance on what is required from pharmaceutical manufacturers.

PREDICTION 4: USP compounding regulations could go into effect.

In June 2019, the United States Pharmacopeia (USP) released several new and revised pharmacy compounding standards. Some of the critical areas for pharmacy compliance include quality assurance/control, facility requirements, beyond use dates, and personnel qualifications. Regulatory oversight and enforcement of these areas belong to multiple agencies, depending on pharmacy location and compounding facility, but it is expected that the Joint Commission of Pharmacy Practitioners, state boards of pharmacy, and the FDA will each play a role in compliance.

The USP published the final revised version of General Chapter 797 (Pharmaceutical Compounding — Sterile Preparations) to accompany the previously released General Chapter 800 (Hazardous Drugs — Handling in Healthcare Settings). Due to pending appeals, the effective date of USP 797 remains postponed until further notice, and USP 800 remains "informational" until 797 is finalized. While federal regulatory agencies and accrediting organizations are unlikely to begin enforcement of both chapters until after the appeals process is complete, several state boards of pharmacy have begun enforcement of USP 800, which may affect your pharmacy or health system's timeline for compliance. In 2021, USP 797 has the potential to become regulation and enforceable, but this is dependent on the progress of the current appeals. Pharmacies must comply when the standard becomes official and enforceable. For more information, visit https://www.usp.org/compounding/general-chapter-797.

COVID-19 will continue to shape aspects of our lives in 2021. Pharmacy has an important opportunity to enhance patients' wellness and prevent further spread through community-based administration of forthcoming vaccine(s). Until vaccines are available, wash your hands, stay safe, and have a relaxing and healthy new year! **CT**

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EXAMPLE: COVID-19 VACCINE ADMINISTRATION

The Pennsylvania Pharmacists Association provided an update on steps that pharmacies should complete to prepare for administration of COVID-19.

1. In order to participate in COVID-19 vaccinations, pharmacies must sign the Pharmacy Memorandum of Agreement (MOA).
2. On November 2, the Pennsylvania Department of Health (DOH) will be contacting all pharmacies that have already signed the MOA with an official request to:
   a. Sign and submit the COVID-19 Vaccine Amendment to the MOA to the DOH. This amendment will be attached/linked to the email communication with instructions on where to send it.
   b. Complete the provider agreement forms — both Section A and Section B. The web form is preferred over the fillable PDF, since it goes directly into the Pennsylvania DOH database.
3. Additionally, the Pennsylvania DOH requires completion of a one-hour training module from the CDC, "You Call the Shots — Storage and Handling." Pharmacists can receive CE credit for completing this training.