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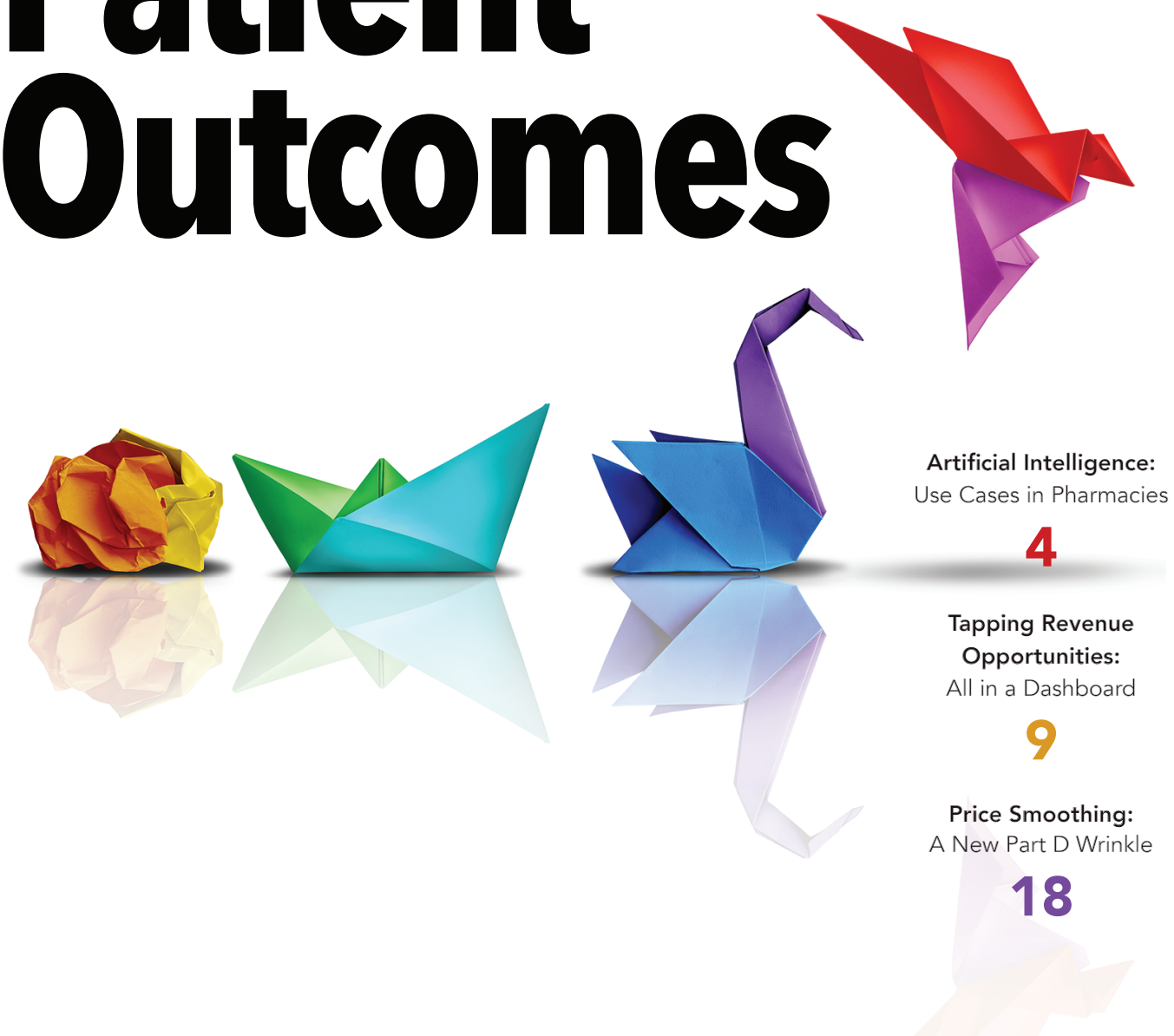
FOR THE PHARMACIST

Managing and Improving Patient Outcomes



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ComputerTalk:
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Managing and Improving Patient Outcomes

by Will Lockwood

ComputerTalk's special report on managing and improving patient outcomes. We look at what's successful for pharmacists and the areas where they see opportunity.

story begins on pg. 5

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What's It All About?

THE FOLKS IN WASHINGTON COOK UP ALL SORTS OF REGULATIONS for Medicare Part D prescriptions. These put new financial burdens on those responsible for dispensing these prescriptions, namely pharmacies.

Let's start with direct and indirect remuneration (DIR). This regulation makes it difficult for pharmacies to know what their reimbursement will be until well after the fact. This is about to change with providing this in real time at the point of dispensing when real-time reporting kicks in in 2025. I am intrigued by the DIR label. What does indirect remuneration mean? And what's the difference between this and direct remuneration? Who is doing the remuneration? I know the answer to that question. Pharmacies, of course, are the ones doing the remunerating, with the carve-out on their reimbursement. Pharmacy associations have been doing battle with CMS (Centers for Medicare & Medicaid Services) over this regulation since its introduction. But DIR still exists and it's causing pharmacies to close.

Now we have Part D maximum fair prices and price smoothing that pharmacies will have to deal with. These may be beneficial to Part D beneficiaries, but the same cannot be said for pharmacies. Maximum fair prices will have another impact on reimbursement. This was covered in the last issue of *ComputerTalk*. Price smoothing will have an impact on cash flow. You can read more about this in the Viewpoints column in this issue. If CMS isn't careful, a lot of Part D beneficiaries will be left out in the cold as their pharmacies shut their doors, particularly in rural areas where pharmacy locations are sparse to begin with.

All that said, pharmacies need to find other revenue sources to be less dependent on prescriptions for survival. This is one of the reasons there has been so much emphasis of late on promoting pharmacies as providers of clinical services that can be reimbursed. Our cover story in this issue touches on what pharmacies are doing to improve medication outcomes. This is where a pharmacy's vaccine program can be beneficial. It has an outcomes metric as well.

My position is that CMS must cease coming up with requirements that penalize pharmacies. I am not sure how much discretion CMS has, but if a legislative change is necessary, then CMS should push for this. It's that simple. **CT**

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ASAP's mission is to foster understanding of the role that technology plays in assisting pharmacists to promote patient safety and the proper use of medications, comply with laws and regulations, and operate their practices more efficiently by providing a forum for sharing diverse knowledge and perspectives on the modern practice of pharmacy.

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Optimization of Artificial Intelligence

by J. Randall Hoggle, B.Pharm., D.Ph., M.B.A.

MANY EXTERNAL FACTORS CONTROL THE potential of the application of artificial Intelligence (AI) for pharmacies in patient care, business applications, and regulatory compliance programming.

Today's burgeoning AI software development and commercialization is being predominantly targeted for language models with immediate applications in communication and language skills. Additionally, today's AI software development and commercialization initiatives are also targeted for analyzing complex data, imagery, and spatial capabilities for analysis of data and its aggregated enhancement into value-centric applications to provide information.

In the *Washington Post* article entitled "How will AI affect your job?" published May 14, authors Yan Wu and Sergio Pecanha discussed two premises that will determine the speed, depth, and breadth of AI in multiple industries. The first premise is that "most jobs will be affected but all jobs will not be affected at the same rate." This premise is echoed by the OpenAI researchers' approximation that 80% of the U.S. workforce would have its workload tasks impacted by at least 10% by the language models. The more manual the work, the less AI initially will assist.

But where manual work or redundant work is performed, then AI communication and language skills start to be applicable. For pharmacies this premise would then more likely apply to prescription intake, processing prescription filling, communication with patients, prescribing parties, and payers' data related to individual prescriptions.

The second premise advanced by Wu and Pecanha is that complex data, imagery, and spatial analytics could be analyzed more quickly, and patterns developed that could expedite such activities as supply chain product distribution, central-fill functions, and regulatory compliance analysis. Factors that will reduce the speed of implementation in an industry are barriers to adoption. For pharmacy, these barriers include five government agencies having oversight over pharmaceutical product development, manufacturing, supply chain distribution, pharmacy practice, and pharmacy compliance, with pharmacy having the further limitations of data aggregation and analysis due to Health Insurance Portability and Accountability Act (HIPAA) privacy compliance restrictions.

However, pharmacy teams should optimize AI for patient outreach and reporting capabilities as soon as possible, due to the workforce limitations most of you are working under now. Similarly, pharmacies can use AI to expand vaccination programs, increase development of combination practice capabilities to broaden the practice areas, and grow the net revenue to stabilize or grow the business.

The authors referenced above, and many others who cover AI, try to answer the question of "How long before a machine takes over my job and our business"? But most human resources planning experts hesitate to predict the speed at which AI will be implemented. For pharmacy, like many other careers, this will not be the first time new technology has changed how we work.

Most healthcare worker AI occupational exposure data reports have not referenced pharmacy practice yet, and thus we would recommend pharmacy teams participate in surveys of tasks where you would like to see AI assistance developed. The evidence is already available on the value of AI in patient care and safety. These are immediate opportunities to use several AI software packages to address communication and patient follow-up for medication adherence checks and required regulatory compliance reporting requirements. **CT**

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Managing and Improving Patient Outcomes

By Will Lockwood
Vice President | Senior Editor

Will can be reached at
will@computertalk.com

Community pharmacy has been working hard to build the competencies, programs, and technology base to make a real impact on patient outcomes. Here we'll take a look at the technology tools and clinical programs in place at two pharmacies, Mitchell's Drug Stores and Shrivers Pharmacy, that are finding success. There are areas of pharmacy operations and currently available technology that can drive positive outcomes, but we'll see that it takes more than just flipping a switch to be successful.

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BUILDING FROM ADHERENCE

Lacy Epperson, Pharm.D., is the director of pharmacy clinical services at Mitchell's Drug Stores in Neosho, Mo., which operates three community pharmacies and one long-term care pharmacy. One of the community pharmacies is newly opened and runs on a cost-plus model that does not accept insurance, in an effort to reduce costs for patients. "Our adherence programs, beginning with med sync, are the foundation for clinical services," says Epperson. "This is where everything starts for us in our efforts to get the best outcomes for our patients."

Andrea Kowalski, Pharm.D., who is director of clinical services at Shrivers Pharmacy, also views med sync as a foundational program when it comes to managing and improving patient outcomes. Shrivers Pharmacy operates multiple locations in southeastern Ohio and West Virginia, offering retail, long-term care, hospice, durable medical equipment, and 340B.

Lacy Epperson, Pharm.D., director, pharmacy clinical services, Mitchell's Drug Stores, Neosho, Mo.

"Our adherence programs, beginning with med sync, are the foundation for clinical services."

"Medication synchronization is the outcomes-focused program that is most readily available to pharmacies and is easiest to implement," says Kowalski. It is all about establishing a routine in which patients are expecting to have an interaction each month with the pharmacy. From the patient's point of view, it's convenient to pick up all their medications at the same time. For the pharmacy, this doesn't just streamline workflow, but more importantly it creates known opportunities for interacting with the patient and defined times to review care opportunities and offer additional services.

At Shrivers, the med sync workflow is the start of what Kowalksi calls a deeper dive into the patient's care. "We take the opportunity each month to review all their medications against current guidelines," says Kowalski. "We're also making sure that they are up to date on their vaccines and looking for other care opportunities that they can benefit from."

The role that med sync plays as the jumping off point for patient care programs means that you need to ensure you are maximizing the number of patients enrolled. Lacy Epperson says that the traditional benchmark for community pharmacy is an 80% participation rate, a goal that they have reached at Mitchell's Drug Stores. It is, however, important to set med sync program participation goals after taking a pharmacy's patient base into account.

THE 80% GOAL

An 80% participation rate in a med sync program is indeed a good number to start with, because it reflects the typical split between chronic and acute medications dispensed at many community pharmacies. "The commonly cited goal is 80%," explains Epperson, "because ideally you will enroll every patient filling prescriptions for chronic conditions in your med sync program. But the right goal is going to be based on the business model of the pharmacy. Whenever I talk about med sync, I point out that it's not a one-size-fits-all program."

Epperson suggests beginning by answering a few questions. What does the pharmacy's business look like? Does the pharmacy service chronic care patients, or is it located next to a clinic or urgent care center writing a lot of acute prescriptions? In fact, Epperson has different med sync participation rate goals for each of the Mitchell's Drug Stores locations. She reports taking into account the type of practice and the patient demographics. But once you can set and achieve an appropriate med sync program participation goal, Epperson emphasizes, a robust program really opens the door for many other opportunities for clinical services and for bringing order to pharmacy operations. "A solid enrollment level in our med sync program helps us to structure our workflow, understand our scheduling better, and really to gain a better level of control of our very busy businesses," says Epperson.

continued on page 8

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continued from page 6

Epperson offers one important example about how to use med sync in a creative way that does not fit the standard application to patients on multiple medications. "One common situation we're seeing more," says Epperson, "is patients on expensive birth control or expensive inhalers, but otherwise not chronic care patients. They benefit greatly from being in our med sync program, because we can use the interactions built into that program to ensure that they don't unexpectedly find themselves in need of a refill that leads to a gap in therapy. We will call them ahead of their refill date and make sure that we are taking care of them."

FROM MED SYNC TO CARE SYNC

When there is a strong participation rate in a med sync program, you then have the base for building out further adherence and outcomes focused programs. At Shrivers the goal is to make use of the anticipatable patient visits prompted by med sync as opportunities for longer interactions. "We want to raise the level of our patient interactions to a more therapeutic and clinical level," says Andrea Kowalski. "Med sync means that we are better able to control the flow of people into the pharmacy. If we know that a patient on 15 medications is coming in this week to pick up his prescriptions, then we can be prepared to talk to him about his medications and review any open care opportunities and programs that may improve outcomes."

For example, a patient might be a good candidate for a vaccine. Kowalski reports that Shrivers is currently putting a big emphasis on ensuring that patients are up to date on the Shingrix vaccine.

At Mitchell's Drug Stores, Epperson reports that the goal is to build from med sync to what she calls care sync. "We work hard to standardize all the elements of our programs and create very efficient processes that offer a wide range of care opportunities," she says. "We call it care sync to recognize the fact that what we are doing goes above and beyond providing patients with medications."

Epperson breaks down the efforts at Mitchell's Drug Stores into three key elements: The first, as we've learned, is traditional med sync. The second is adherence packaging, with both strip and bubble card options. The third is a new and quickly growing medical-at-home program. "Medical at home combines med sync and packaging with extra clinical services appropriate for patients in need of the higher levels of care that you would normally see in a long-term care setting," says Epperson. Then, on top of these core care services, there are many

continued on page 10

Revenue Opportunities: All in One Place

In this interview with ComputerTalk*, Alexander Miguel, Pharm.D., chief operating officer for Transaction Data Systems, explains how a new dashboard gives TDS customers quick access to $1 million worth of revenue opportunities from clinical services.*

ComputerTalk: What are a few of the key new features of the clinical opportunity solution?

Alexander Miguel: Opportunities Now is our new clinical opportunity solution and is a dashboard where all of a pharmacy's aggregated clinical revenue opportunities are in one place. This will allow pharmacists to see all the opportunities in workflow. This platform will bring in opportunities from different clinical services providers as well. For example, we have partnered with OutcomesMTM, and our pharmacies can see all the Outcomes clinical work that is related to their pharmacy, and the patients that go to their pharmacy, in the dashboard. Just from that partnership alone, for example, this month, there are over $1 million in clinical opportunities available to pharmacies across the TDS network.

ALEXANDER MIGUEL

CT: Which is pretty amazing.

Miguel: Yes! One thing that really differentiates TDS is that we are focused on bringing as much new revenue to our customers and to our partners as possible and making sure that we aggregate it all in one place. We want to drive the most value possible from one dashboard. So, whether it's a clinical or pharma program that we have partnered directly with, through our partnership with Outcomes, or through a medical billing partnership, everything we're doing is in one place for our customers.

CT: That's important, because in the past the pharmacist would have had to find those opportunities on their own.

Miguel: Not only is it consolidated in one place, they can also sort it by highest revenue opportunity to lowest. There are filters where they can sort by the type of work, such as an adherence intervention or a vaccine, or the patient's next refill date to time the clinical work with the expected presence of the patient in the pharmacy.

CT: We think it's important — to be able to communicate with customers as far as making them aware that a clinical opportunity exists.

Miguel: Absolutely. For example, there are over a hundred million vaccine opportunities across our network. Timing those vaccines with the patients coming in for refills is critical to being able to deliver them. With Opportunities Now, the pharmacist can see when that next refill is and what vaccines that patient may be eligible for, all in one place.

CT: We want to ask about documentation and communication. Not only is the opportunity streamlined, but it seems that a big part of this is being able to document and share that information.

Miguel: With Opportunities Now, pharmacies can document the work that they're doing within that window. They can click into the alert or the clinical opportunity that's being presented and document that it was completed. That produces a data file that's sent back to the sponsor who's paying for the work.

CT: The advantage is having everything in one place and not having to piece it together.

Miguel: I think that it is unique not only that all the information is in one place, but also that the aggregation makes it easy for the pharmacy to implement as a daily part of its practice. There are not just one or two interventions, which might feel like it's a waste of time to go in and do the work. There are a lot of interventions per pharmacy. And that should hopefully give the pharmacist the operational leverage that they need to make this part of their everyday procedures.

CT: What else are you excited about with this?

Miguel: What's exciting is having the most aggregated volume of opportunities in the market by far. The next step for us is to have this integrated into our pharmacy management system. That will allow for that streamlined workflow I was referring to, which means when an Rx30 or Computer-Rx user pulls up a patient's profile, he or she will be able to see the clinical interventions that are an opportunity now. Within the PMS workflow, pharmacists can click on and do all the documentation they need. That way, when a patient walks in, not only is the pharmacist looking at their drug profile, but they are also looking at the clinical service profile.

CT: This reinforces the long-time effort to get pharmacists out from behind the counter.

Miguel: The idea is, again, shifting that practice of pharmacy toward a clinical-first pharmacy. Being a clinical-first pharmacy management system provider, we realize that's a long way away. There's still a lot of dispensing activity that a pharmacy must do, and it's the core of their business, but the transformation has to start somewhere. And we really believe that it starts here at TDS. **CT**

continued from page 8

different clinical service programs that Mitchell's Drug Stores can offer patients, which include diabetes care and vaccine clinics, according to Epperson.

SUCCESSFUL PROGRAMS

Andrea Kowalski points to a behavioral health monitoring program at Shrivers that has been making a big impact on outcomes since 2020. "This program focuses on patients taking an anti-anxiety med or an antidepressant," she explains. Pharmacy staff use a PHQ-9 and GAD-7 (Patient Health Questionnaire and General Anxiety Disorder) questionnaire to assess current anxiety or depression levels. Based on the results, Kowalski reports, Shrivers can then counsel the patient to ensure that they understand how their medications work or even, on occasion, reach out to prescribers with recommendations.

Shrivers then makes follow-up calls to patients and readministers the test as appropriate. "The use of the assessment questionnaire in this program gives us a tangible measure of how we're helping patients manage mental health," says Kowalski. "We have found that patients really do want to talk with us about their mental health and their medications. And as we monitor the assessment scores over time we are able to demonstrate that having this interaction with a pharmacist is really beneficial for those patients."

Andrea Kowalski, Pharm.D., director, clinical services, Shrivers Pharmacy

"The use of the assessment questionnaire in this program gives us a tangible measure of how we're helping patients manage mental health."

Kowalski offers several more examples of counseling services that Shrivers offers that help achieve better outcomes. "We offer diabetes care," says Kowalski. "We talk to patients about their glucose levels and their medications with the goal of ensuring that they understand everything that goes into managing their diabetes on a daily basis."

For another example, Kowalski notes that the pharmacy has, at times, had payers that would provide at-home blood pressure monitors for patients with hypertension. "We would show the patient how to use the monitor and educate them about their medications," says Kowalski, "and then call them at home to check on the readings. This was really helpful during the pandemic, and it shows that the pharmacy can have a positive impact on patient health and outcomes whether we see the patient in person or check in remotely."

SETTING GOALS, STANDARDIZING PROCESSES

Lacy Epperson has found that the best outcomes come when two things are true of a pharmacy's operations. First, the pharmacy needs to have well-defined processes and the right technology in place to support programs and service offerings. Second, it is important that staff are educated on how to use the technology appropriately to meet the pharmacy's care goals.

The technology suite for adherence programs at Mitchell's Drug Stores starts with the med sync features in the PioneerRx pharmacy management system, according to Epperson. Then the pharmacy adds adherence packaging, with effective integration to the pharmacy management system. "We use strip packaging automation from RxSafe," says Epperson. "And we also use Dispill blister packaging. We're moving away from that because we can streamline and automate much more successfully with strip packaging automation, and it's more convenient for our patients."

The benchmark, whichever technology providers a pharmacy uses, is that staff can easily navigate workflow steps, for example to pull patients into a certain med sync cycle or to add them as a medical-at-home patient. "You want to know that you can take these steps very quickly, efficiently, and correctly," says Epperson. "The technology also has to be easy to teach. I'm not a tech guru, but I can still teach anyone on my team to use our technology to implement our programs."

Epperson is a firm believer that it is easiest to use pharmacy

continued on page 12

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continued from page 10

technology when pharmacy staff understand the goals of the process. For example, the task may be to dispense a short fill for a prescription, but that one step is actually part of a series of goals. "The immediate goal is to use the short fill to sync the medication with all others for the patient so that he or she has one pickup date each month for all prescriptions," says Epperson. "When this is the case, then our goal is to sync up provision of services for that patient as well. We are then able to achieve our highest-level goals, which are to be as efficient as possible in the pharmacy, to ensure that we address all elements of the patient's overall care, to make a positive impact on outcomes, and to provide the highest level of customer service."

Epperson reports a recent addition to Mitchell's Drug Stores technology capabilities that's had a positive impact. "We added what I see as a very productive feature about six months ago," she says, "which is an option for patients to receive a HIPAA-compliant link to fill out a questionnaire before receiving their medications for the month. They can tell us about any changes they've experienced and if they need anything that is not a monthly medication, such as an inhaler, nausea medication, or a cream. We are seeing a high response rate to this new patient touchpoint compared to phone calls, because it's easier for many of our patients to be able to click that link on their lunch break or at home when the pharmacy isn't open. This is a really integrated process that has not required a lot of time for us to implement."

MEETING CHALLENGES

While modern pharmacy systems and automation are rich in features that improve outcomes through dispensing oriented programs such as med sync and packaging, Andrea Kowalksi notes that there's still a gap in the market when it comes to documentation and billing for services. "This has been one of the biggest challenges for us," says Kowalski. "Developing and implementing programs that improve outcomes has not seemed nearly as difficult as documenting and billing for them."

As a result, Kowalski has worked to develop in-house tools that combine with features in Shrivers' Rx30 pharmacy system to meet the pharmacy's needs. "When we first started with the clinical services," says Kowalski, "I developed intake forms that the pharmacist would print and fill out with a pen. They would fax that to our corporate office, where we had somebody who would enter that data and bill for it. Then the pharmacist also would go in and complete an eCare plan in Rx30 as well. That was a lot of extra steps and a lot of paper. More recently I have developed an electronic intake form that our pharmacist can fill out and submit that goes directly to a live spreadsheet that houses all the data for these encounters."

Pharmacists are still filling out a Pharmacist eCare Plan separately. "It's still not ideal," says Kowalski. "I think that the market is aware of the need for better tools for documenting and billing for service, but we haven't found the perfect solution yet at Shrivers."

This centralized spreadsheet is also a help in Kowalski's work to get the word out about the importance of clinical programs in improving outcomes. "I'm writing a research paper on our behavioral health services," she explains. "Now that I have that data in electronic form, I can pull out what I need and analyze it much more readily."

PHARMACISTS IMPROVE OUTCOMES

Getting the best outcomes means having the systems and processes in place that enable a pharmacy to meet the different needs of large numbers of patients. As Lacy Epperson notes, you want your technology to support the workflows that move patient care toward your goals seamlessly.

"We are getting better outcomes and we see that through higher true adherence rates, not just our fill rates," says Epperson. "The flip side of this is that, for patients who are not adherent, we are able to identify them much more easily and focus on the critical interventions that we need to make with them. We know that this is impactful, and it is something that we can excel at as a truly local and independent pharmacy." Once you develop a program that is truly outcomes focused, you have a repeatable process and a consistent touchpoint with your patients each month. You are also strengthening relationships with providers in the community, notes Epperson. "Providing an extra level of care can be something unique to independent pharmacies," she says.

"It's really hard for many people to access healthcare," adds Andrea Kowalski. "There are so many underserved patients. Our goal at Shrivers is to fill in the gap, and that means doing much more than just dispensing prescriptions. We achieve the best outcomes when our pharmacists are also stepping in to help with clinical programs and services." **CT**

Pontem Health Solutions: A Focus on Patient Outcomes

ComputerTalk *Publisher Bill Lockwood sits down with Patrick and Eric Davis to hear about the focus of Pontem Health Solutions, located in the Pittsburgh metro area, and their system Patient Health Flow (PHF). Patrick is director of operations and Eric is the finance director.*

ComputerTalk: Let's start with how you came up with the idea for Patient Health Flow.

Patrick Davis: We achieved our specialty accreditations in 2017 and began servicing disease states where the patients are traditionally underserved and marginalized. We began to recognize barriers that existed in care that could be overcome by free lines of communication through all involved in that patient's health journey.

Patrick Davis

Eric Davis: We were utilizing multiple platforms and software suites to meet accreditation standards. We found that these fragmented solutions created additional barriers that hindered the end care of our patients. The development of Patient Health Flow was organic and specific to delivery of care to our patients.

CT: Now a little on your backgrounds.

Eric: Our father is a pharmacist whose passion is independent retail pharmacy. We grew up watching him build a successful independent pharmacy that focused on patient health and well-being first. We both took different career paths that ultimately led back to providing a high level of care at community pharmacies. We took his mindset on patient care and made it our underlying focus on all pharmacy operations.

CT: Give us the specifics on how your product can benefit pharmacies.

Eric: Patient Health Flow allows the pharmacy to focus its efforts on what actually impacts the patient's health outcomes, while exceeding industry standards. It breaks down communication barriers between all providers while eliminating duplicate care steps.

Patrick: Too many times independent pharmacies have gone above and beyond for patient needs but have not been able to quantify their efforts. Our software allows the pharmacy to prove payer value through data-driven metrics that are gathered and shared in real time. PHF is a platform that allows you to demonstrate and prove your efforts in providing patient care on multiple levels. This helps independent pharmacies gain access to closed and restricted networks.

CT: Tell us more about your vision on seamless patient care and how the use of data can break patient barriers.

Patrick: By providing immediate and transparent communication between all parties involved, we were able to utilize data in a way that broke down barriers that would normally hinder the patient's experience and negatively impact outcomes. There are times when the physician, pharmacy, and payer all have different contact information for locally transient patients. This can create gaps and delays in patient care. The ultimate cost in this scenario is the loss of a positive therapy outcome. Patient Health Flow can connect all parties involved by sharing information and simplifying the patient experience. A care cycle should be seamless and continuous — it shouldn't be steps with barriers.

We can also use data to proactively prevent breakdowns in care for certain scenarios. Recognizing what steps need to be taken with a patient to avoid therapy failure can allow for a customized care cycle that best fits individual needs. Every patient who walks through the doors of a pharmacy has a different story and different needs. PHF allows you to be attentive to those specific needs at the start of care, not reactionary to an issue that arises during therapy.

Eric: Data generated through patient care should not be viewed as a commodity. It should be used as a tool to drive positive outcomes in care and increase value to the payers. When we developed PHF we would often ask ourselves "How would we want our grandparents treated?" We used this as a measuring stick for what we wanted the software to achieve.

Eric Davis

CT: Have you made any progress with your product's integration in pharmacy systems?

Patrick: Yes. We have full read/write integration with multiple dispensing systems. This allows for the data grab to occur in-house at the server level rather than using switch-level data.

CT: Is there anything else you would like to add?

Eric: Patient Health Flow continues to evolve as a tool that includes AI [artificial intelligence]-driven audit protection and support; 340B third-party administrator functionality, where we can complete the necessary reporting for covered entities as well as perform audits for claim accuracy; and direct patient communication. Care should be impactful, but accessible and easy for the patient. It all comes back to what our father taught us — the patient comes first. **CT**

ASAP: Defining Industry Standards

ComputerTalk *Publisher Bill Lockwood talks to Lisa Miller, current president of the American Society for Automation in Pharmacy (ASAP), about the accomplishments of the organization and the benefit of membership. Lisa is senior director of product operations at Pittsburgh-based SoftWriters.*

ComputerTalk: Let's begin with the number of years you have been a member and the value you have gotten out of being a member.

Lisa Miller: I have been a member of ASAP since 2012 and an active board member since 2017. When I think about the greatest value in being a member, two things instantly come to mind. First, the networking opportunities. It has allowed me to connect with other professionals in our industry, share experiences, and exchange ideas. Second, the ability to be able to influence the direction of our industry by being part of defining the standards that we use today.

CT: Becoming the president of the organization is something well deserved. How do you see the future of ASAP evolving?

Miller: I was honored to step into the role of president earlier this year. The field of pharmacy automation is constantly evolving. I believe that ASAP will continue to participate in advocacy efforts aimed at promoting the benefits of automation in pharmacy. By collectively influencing policies and regulations, our members can help shape the future of pharmacy automation. There has been some discussion with the Office of the National Coordinator for Health Information Technology (ONC) to map the ASAP web services and the reporting standard to HL7. However, they have faced some challenges with not all data elements having fields to map to, so it will be interesting to see how this plays out.

Lisa Miller
Senior Director of Product Operations, SoftWriters

"By collectively influencing policies and regulations, our members can help shape the future of pharmacy automation."

CT: ASAP's niche is prescription drug monitoring programs (PDMPs). The ASAP reporting standards developed over the years are used by every PDMP. Tell us more about this.

Miller: ASAP is recognized as a standards development organization by the Office of the National Coordinator. We have continued to grow and mature the standard over the years. The current standard, v4.2B, has been out for over three years, and we recently saw an opportunity to evolve the standard to better suit the needs of the industry today. Starting in Q3 of 2022, more than 40 stakeholders, including PDMP administrators, pharmacy system vendors, and drug chains, participated in conference calls to discuss ways to enhance the data being reported. As a participant in these calls, I was extremely impressed to see the commitment and collaboration that came from the industry, particularly the relationship that we, as an organization, have built with the state PDMPs. The result of these calls was the new v5.0 standard. It includes 44 new fields to address challenges with compliance monitoring, data integrity, and patient matching. In addition to the new fields, new codes were added to existing fields to increase the granularity of the data. Version 5.0 of the reporting standard was released in March, and the industry can begin using it in production beginning Jan. 1, 2024. Several states and system vendors have already ordered a copy, which can be obtained by going to asapnet.org. At SoftWriters, we have already begun the implementation of the new standard and are excited to see the impact that it will have on our industry come January.

CT: And now an ASAP standard is used by one state, Nebraska, to capture all prescriptions dispensed, with others considering doing the same. Would you care to comment on the importance of this?

Miller: There is so much value in the data that is being reported using the ASAP standard. Providing data for all prescriptions, not just controls, enables access to comprehensive patient medication histories, facilitating better care coordination and communication among healthcare teams. I hope to see more states follow Nebraska's lead and make the reporting of all prescriptions required.

CT: Changing direction, let's talk about the annual conference the organization holds and the benefits of attending.

Miller: Our 2024 annual conference will be held January 10–12 at the Don CeSar in St. Pete Beach, Florida. The annual conference offers ample time for networking, with a dedicated afternoon for networking session and a reception. It provides a great selection of presentations, with topics ranging from regulatory updates, best practices, and emerging trends in the industry. New for this upcoming conference, the registration fee is only $500 with a corporate membership.

CT: Any closing comments you would like to offer?

Miller: Being a member of ASAP provides you with the network, knowledge, and voice to advocate for improvements in technology and interoperability in our industry. I love being part of this organization and look forward to seeing familiar faces and meeting new members at the conference in January. **CT**

Artificial Intelligence Chatbots: Applications in Healthcare

Brent I. Fox, Pharm.D., Ph.D.

IN THE LAST ISSUE, I INTRODUCED — AND HOPEFULLY CLARIFIED — large language models and artificial intelligence (AI) chatbots, which collectively are the most talked about technologies today. For those who may have missed the last issue, here is a very brief review. Chatbots are a type of artificial intelligence that we interact with when we use the "Help" feature on a website. The responder on the other end of our question is a computer that uses the text of our question to make an intelligent guess of what we want to know. This type of chatbot has a limited number of questions/prompts to which it can respond. Large language models (LLMs) enable artificial intelligence chatbots like ChatGPT and Med-PaLM (more to come) to have conversational interactions with individuals via submitted questions. Compared to the typical help feature chatbots, large language models enable ChatGPT and Med-PaLM to respond to a much greater and more complicated range of questions/requests. If you are interested in digging deeper into the details of large language models, check the May/June issue of *ComputerTalk*.

Speaking of issues to check out, a recent issue of *JAMA Internal Medicine* contains a very interesting article describing a research project that compared chatbot and physician responses to questions submitted by patients (https://bit.ly/3XuuPiA). Using 195 questions submitted by unique individuals to an online social media forum to which a verified, unique physician had previously responded, the researchers compared the physician's original response to a response generated by ChatGPT (version 3.5). Responses were compared on the basis of the quality of the response and the empathy provided in the response. In nearly 79% of cases, evaluators preferred the chatbot responses over physician responses. In terms of assessment of quality, chatbot responses were rated an average 4.13, while physicians' responses were rated an average 3.26 (1-5 scale, with 5 being "Very Good"). Looking at empathy ratings, chatbot responses averaged 3.65, while physician responses averaged 2.15 (1–5 scale, with 5 being "Very Empathetic").

The study described above provides an interesting starting point to consider potential roles of chatbots (enabled by large language models) as tools to support healthcare professionals. Maybe a chatbot can provide an initial response to a patient inquiry. The patient's provider then reviews/edits/approves of the response, as deemed appropriate. A review of some existing efforts to integrate ChatGPT into healthcare provides insight into the potential future of this technology. However, before I dig into existing efforts, it is worth noting that the evolving nature of both the technology and its uses in healthcare point to an uncertain intersection of the technology and concerns over patient privacy.

INTEGRATIONS WITH HEALTHCARE

A review of existing ChatGPT integrations in healthcare begins with medical transcription. Consider a medical transcription tool for the range of patient encounters. It enables a highly automated method to address a time-intensive task for physicians — documentation. Existing use cases include transcription of in-person and remote patient interactions. Another existing use of ChatGPT provides clinical assessments based on patient-specific information and primary literature, providing a mapped presentation of relevant clinical information. The goal is

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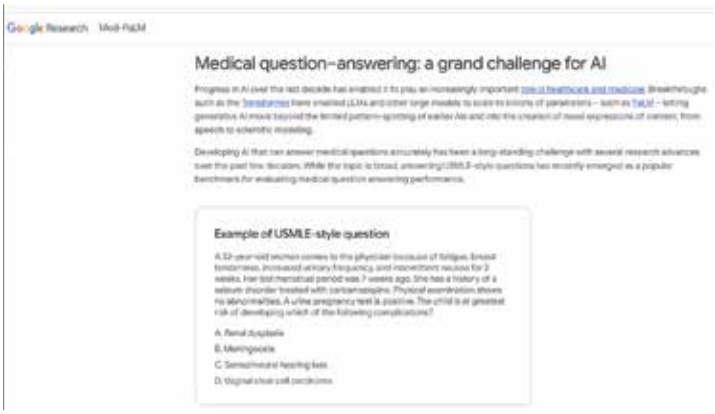
to present a clinical patient summary to the provider, who can then use it in their patient care encounters. Another current use of ChatGPT technology includes personalized app-based coaching to help with intermittent fasting. An additional, very interesting use of ChatGPT enables individuals to ask questions about their health risks, medications, etc., and receive responses based on their genetic profile. Certainly, this last example raises the concerns over patient privacy mentioned above.

Sticking with the healthcare sector, large language models powering AI chatbots like ChatGPT are trained using extremely large amounts of internet-based text. The content and topical areas of this text range across a variety of domains and are not specific to healthcare. However, Med-PaLM from Google is intended for use in the healthcare domain. According to Google Research, Med-PaLM is "designed to provide high quality answers to medical questions" (see image below). While Google does not — understandably — explicitly describe how they designed Med-PaLM for the healthcare domain, the company does indicate that large language models for healthcare require a focus on safety, equity, and bias to protect patients. In one effort to assess accuracy, Google's Med-PaLM 2 answered a series of United States Medical Licensing Examination-style questions. The USMLE is the licensure examination for medical doctors in the United States. According to Google, Med-PaLM 2 scored greater than 85% on the questions, which was a 19% increase over Med-PaLM. Both versions of Med-PaLM exceeded the passing score of 60%.

A commonly cited use case for AI chatbots in healthcare is to research medical conditions or questions. Considering the vast amount of medical information found in journals, textbooks, and similar authoritative sources, this use case makes sense and is highlighted by the *JAMA Internal Medicine* example above. But what about other opportunities? Where might AI chatbots like Med-PaLM fit? At the patient level, many suggest that the accuracy and efficiency of diagnosing medical conditions can be improved. In this space, we have previously written about a movement in healthcare to open the medical chart to patients. Similarly, AI chatbots may be leveraged as tools to provide patients with detailed information about their medical diagnoses and conditions, as well as their medications.

Precision medicine is intended to use a patient's unique genetic information to identify and select targeted medical treatments. Large language models that power AI chatbots like Med-PaLM 2 are envisioned as enablers of precision medicine due to their ability to identify patterns in large data sets. Speaking of large data sets, the public health sector is also a potential area of contribution. Here, the LLM analyzes vast amounts of public health data to identify relevant health trends or patterns.

The list of expected contributions for LLMs in healthcare extends beyond those provided here. *ComputerTalk* readers can probably name many potential areas where LLMs can be leveraged in healthcare. However, it is important to note that this is an emerging technology whose use in the healthcare space requires extensive real-world testing and validation. A single error in a patient care scenario can have significant — and potentially fatal — effects on the patient. One area of low-hanging fruit for LLMs in healthcare is summarizing the vast amounts of medical literature. Even in that use case, where is the liability if an error in summarization leads to a patient care decision that has a negative impact on a patient? Despite the clear questions in front of us, the potential applications and exploration of LLMs in healthcare are not going away. I am looking forward to seeing where this technology fits in the healthcare landscape. Please feel free to send me questions or comments. **CT**



A sample page from Med-PaLM (https://sites.research.google/med-palm/). Where might AI chatbots fit in healthcare and patient care?

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Medicare Part D Price Smoothing

Ann Johnson, Pharm.D.

Patricia Milazzo, R.Ph.

Logan Graham

MUCH OF THE NEWS ABOUT THE INFLATION REDUCTION ACT (IRA) has focused on negotiated prices, vaccine coverage, biosimilar reimbursement, and the insulin payment cap; we covered these topics in a previous issue of *ComputerTalk*. However, an important component of the IRA, out-of-pocket price smoothing, is largely flying under the radar. We will explain this component, which is still open for public comment and may change; the final ruling is expected in the spring of 2024.

PROPOSED IRA REQUIREMENTS RELATED TO PRICE SMOOTHING

If approved, the price smoothing proposal would assist Medicare Part D beneficiaries in managing their out-of-pocket spending and would go into effect Jan. 1, 2025. The proposal introduces a maximum out-of-pocket cap of $2,000 per year. The out-of-pocket price smoothing feature is a benefit that allows participants to pay their out-of-pocket costs over the course of the plan year. Part Medicare D plans are required to offer price smoothing to all enrollees; however, enrollees are not required to participate. The goal of the program is to "smooth" the member's costs over the plan year to avoid experiencing a considerable, and sometimes unaffordable, out-of-pocket cost, generally in the beginning months of the plan year. Opting into the program will not affect how enrollees move through the Part D benefit or what counts toward their deductible or annual out-of-pockets threshold.

As proposed, the maximum out-of-pocket cost for the first month is equal to the out-of-pocket maximum ($2,000) minus the out-of-pocket costs incurred by the beneficiary to date, divided by the number of months remaining in the plan year. The out-of-pocket maximum in following months would be calculated by taking the sum of any remaining out-of-pocket costs owed by a beneficiary that have not yet been billed to the beneficiary, divided by the number of months remaining in the plan year.

STAKEHOLDER CONSIDERATIONS

Medicare beneficiaries may enroll in the program at annual enrollment, prior to the beginning of the plan year. The Centers for Medicare & Medicaid Services (CMS) also recognizes that a new prescription for an expensive medication could occur at any time during the plan year, in which case price smoothing could benefit the member. To account for these instances, CMS has made a provision that patients may enroll during the year.

From a plan perspective, Part D plans are responsible for providing information on the out-of-pocket smoothing benefit and educating potential enrollees. If a patient fills a prescription for an expensive drug and could potentially benefit from smoothing, the patient's plan is required to notify the patient's pharmacy. This could occur at any point in the calendar year. The pharmacy must notify the patient upon receipt of the plan's communication of the out-of-pocket smoothing opportunity and communicate out-of-pocket financials to patients.

Plans are also responsible for accurately calculating the out-of-pocket expenses. This includes calculating a patient's annual deductible, taking multiple prescriptions copays and out-of-pocket expenses into consideration. The plan must also transmit this information to the pharmacy during the adjudication process.

If the patient is eligible for smoothing and chooses to accept the plan's smoothing option, the pharmacy may be responsible for enrolling the patient. How pharmacies would handle enrolling patients is yet to be determined.

REIMBURSEMENT

Pharmacy reimbursement details are vague. The legislative

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text includes a provision that Part D plans "shall ensure that such an election by an enrollee has no effect on the amount paid to pharmacies (or the timing of such payments)." Pharmacy reimbursement should not be reduced, but cash flow may be impacted. One scenario suggests that plans will act as the creditor, fronting the full out-of-pocket cost to the pharmacy on behalf of their members. Plans will have to implement processes to bill and collect payment from enrollees who opt into the smoothing program. There is only vague language surrounding how plans should handle enrollees who fail to pay smoothing costs. If a patient fails to pay an out-of-pocket smoothing cost billed by their plan, the plan has the option to remove them from the out-of-pocket smoothing benefit for the rest of the plan year and may preclude participation in the subsequent year. It is unknown if a plan can exclude a member from enrolling in a smoothing benefit if they previously did not pay smoothing costs on a different plan in previous plan years.

A second scenario places the pharmacy acting as creditor, with the plan reimbursing the pharmacy over the course of the year, as opposed to current prompt-pay rules. The pharmacy would incur the purchase and dispensing expenses up front but would receive payment gradually over the course of the calendar year. Due to declining reimbursement rates, pharmacies are unlikely to voluntarily agree to this scenario.

It will be interesting to see how plans navigate this legislation. It is in their financial best interest to be unforgiving toward missed payments, but will there be an appeals process for special situations? If a member is hospitalized and misses a payment, will they be removed from the smoothing benefit by their plan? Will plans use strict criteria to determine who can benefit from out-of-pocket smoothing to limit awareness, enrollment, and financial risk? These are all questions that will need to be answered.

TECHNOLOGY ENHANCEMENT NEEDED

Pharmacy adjudication systems will require enhancements, primarily surrounding the communications required between the plans and the pharmacy. The specific new data components required for financial and enrollment data remain unclear but should be anticipated. The National Council for Prescription Drug Programs (NCPDP) has initiated a task group to identify and update the Telecommunication Standard to include new codes for plan-to-pharmacy required communications and is expecting that new financial codes will be required.

ADDITIONAL CONSIDERATIONS

The out-of-pocket price smoothing will distribute the out-of-pocket costs to members who are on a plan and medication for 12 months, but there will also be situations where a member may initiate an expensive specialty medication in the late months of a plan year. Since the remaining months in the plan year are used to calculate the maximum out-of-pocket cost, that member would be subject to exactly what the IRA is trying to avoid, a high out-of-pocket cost. The same is true for a member who may switch or escalate therapies to a more expensive alternative later in the year. It has been proposed that the unpredictability of the out-of-pocket price smoothing program could be remedied by altering the calculation for the monthly out-of-pocket maximum cost, distributing the costs over the next 12 months, instead of the remaining months of the plan year. This solution introduces additional issues. Should a member change Medicare plans, they may still owe their previous plan sponsor. The previous plan would be tasked with billing its former member. Since the member already received their medication and is on a new plan, there may be less incentive for the member to pay their former plan. There are pros and cons to both methods that need to be weighed carefully.

All unanswered ethical and operational concerns will need to be addressed prior to the proposed implementation date. Stakeholder discussions with CMS about these concerns, as well as conversations surrounding the needed technology enhancements, are imperative. Luckily, there is still time to find the best approach to the out-of-pocket smoothing program before it is implemented in 2025. From now until the fall of 2023, stakeholder engagement will continue with CMS on the implementation of the out-of-pocket smoothing programs. Between the fall of 2023 and February 2024, proposed Medicare Part D rules, with details regarding the implementation of out-of-pocket smoothing programs, are expected to be released. CMS is expected to make the final rule between by April 2024 before the program goes into effect on Jan. 1, 2025. The fine details of the program still need to be thoroughly considered before the program can run smoothly. **CT**

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What Will the Fall Bring?

Marsha K. Millonig
B.Pharm., M.B.A.

WHILE MOST OF US ARE STILL ENJOYING the summer, health officials and pharmacy organizations are already gearing up for the fall immunization season at a quick pace. Training has been assigned, and pharmacies are actively setting up flu clinics in anticipation of a high-demand vaccination season after last year's "tripledemic" of influenza, COVID-19, and respiratory syncytial virus (RSV). Many people heard of RSV for the first time last year, given its widespread impact last fall and winter. Others are learning about it for the first time since the Centers for Disease Control and Prevention (CDC) recommended RSV vaccines from Pfizer and GSK in June for people 60 and older. With the U.S. Food and Drug Administration (FDA) approval of the RSV vaccines, health officials are encouraging people to get three vaccines this fall: influenza, COVID, and RSV for older adults.

The New York Times

Federal Officials Hatch a Three-Pronged Defense Against Another 'Tripledemic'

This fall, Americans will be urged to get shots against the flu, Covid and, if they're older, R.S.V.

The July 5 *New York Times* article by Apoorva Mandavilli. The author explains why the federal government is recommending the three vaccines this winter. See www.nytimes.com/2023/07/05/health/vaccines-rsv-covid-flu.html.

RSV ON THE RISE

First, a bit about RSV. RSV is a viral illness that impacts the respiratory tract, causing mild, cold-like symptoms. While the majority of those infected feel better in week or two, RSV can be very serious for infants and older adults. The CDC notes that almost all children will have had RSV by their second birthday. Older adults who have chronic conditions affecting the heart and lungs, who are immunocompromised, or live in long-term care facilities are at higher risks for serious problems from RSV. Consider the facts about the annual burden of RSV:

- 58,000–80,000 hospitalizations among children younger than 5 years.
- 2.1 million outpatient visits among children younger than 5 years.
- 100–300 deaths among children younger than 5 years.
- 60,000–160,000 hospitalizations for adults 65 years and older.
- 6,000–10,000 deaths for adults 65 years and older.

This compares to last year's flu season data of 12–26 million medical visits, 300,000–650,000 hospitalizations, and 19,000–58,000 deaths.

While RSV's burden is less than influenza, it is still high. And now there is a vaccine to afford protection. The vaccine has not yet been approved for pregnant women, but that is expected later this summer because research is finding vaccination later in pregnancy confers antibodies to the infant.

On the COVID front, the FDA's Vaccines and Related Biological Products Advisory Committee has asked vaccine makers to reformulate their products to include protection from a new variant, XBB.1.5, for this fall, and that it be updated as a monovalent vaccine. Currently, older adults can decide whether to get a second booster of the bivalent vaccines that were introduced last year. Only 43% of adults 65 years or older decided to get the bivalent vaccine last year, compared to 71% who received the flu vaccine. There is definitely a group of proactive older adults who call the pharmacies I staff wondering if there is a "new" COVID vaccine or whether they need another of the bivalent. Many of my fellow quilt group

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members asked me about this topic at our summer picnic. I am certain these individuals will also be asking about the RSV vaccine.

Ofer Levy, who heads Boston Children's Hospital's precision vaccines program and is an FDA advisor, said in a recent *New York Times* article that the new RSV vaccine is a "godsend" and is an important tool that can be deployed to keep people from losing loved ones.

POTENTIAL BURDENS OF ADDITIONAL VACCINE PROGRAMS

While I am happy to see the news about the RSV vaccine, I am extremely concerned about the burden an additional vaccine will place on the pharmacy staff this fall, for a number of reasons:

1. Is there sufficient time to educate both patients and providers about the benefits of the new RSV vaccine? Do we know how the vaccine should be administered and stored? Will there be an adequate supply, given this is the first time a vaccine for RSV is available? Are there special considerations or potential side effects? As with other vaccines, can it be given at the same time as those for COVID and influenza? How will payers reimburse for this vaccine? Will they cover pharmacy administration?
2. When is the new monovalent COVID vaccine formulation expected? Weeks from now? Months from now? Before the flu vaccine season really gets underway in mid-to-late September? How quickly will we be able to adapt to the new vaccine and remove supplies of the current bivalent from the pipeline if necessary? Will there continue to be indications for the current bivalent vaccine? What will the new recommendations be for each age group? What educational efforts will be undertaken with the public?
3. Will pharmacy organizations have scheduling systems in place that work and ease the burden at the pharmacy counter? For example, systems that allow/require a patient to complete consent forms and provide insurance information when making an appointment, reducing the time spent when they arrive for their appointment? Will the system allow patients to choose multiple vaccines at one time rather than having to make multiple appointments? Can the system process billing for the vaccine prior to the patient's arrival? This can be a time saver, but can also create issues when the prebill must be reversed at the originating pharmacy when a patient decides to go elsewhere.
4. Will pharmacy organizations support staffing levels by requiring appointments and/or limiting times when walk-in vaccinations will be given? Will pharmacy staff have the authority to make that decision based on their location's workload and staffing?
5. What resources can help us educate patients that they can safely receive all three vaccines in one arm? By doing so, the vaccines can be given more quickly and the patient has a more localized area of pain from injections.
6. What messaging will health officials at federal, state, and local levels be sending to the public, and how far in advance will pharmacy organizations be made aware of these communications?

Pharmacy system vendors should be proactive in working with customers to be sure systems can more than adequately handle the possibilities this "new" flu season may bring.

These questions are just those in the front of my mind after reading the *Times* story about the plans for a "three-pronged" defense against another tripledemic. While the new RSV vaccines and forthcoming reformulated COVID vaccines represent important steps in keeping people healthy, I am concerned this "three-pronged" approach will create a triple workload for an already strained pharmacy community. Pharmacy system vendors should be proactive in working with customers to be sure systems can more than adequately handle the possibilities this "new" flu season may bring. **CT**

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