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September 14, 2023 | Web Event Transcript

Will Insurance Cover Over-the-Counter Contraceptive Pills? A Discussion of Coverage Options and Challenges

Laurie Sobel: Hello and welcome to the KFF web briefing, Will Insurance Cover Over the Counter Contraceptive Pills? I am Laurie Sobel, an associate director of Women's Health Policy at KFF, and I'll be your moderator today. As you probably know, this past July, the FDA approved OPill, the first over the counter daily oral contraceptive pill. It is expected to be available early next year in stores and online, but the manufacturer has not yet announced the price. We know from the KFF Women's Health Survey that many people are interested in using OTC oral contraception, however likely users are cost sensitive and useful, depend in large part on affordability as well as insurance and Medicaid coverage.

As I assume most of you know, the ACA requires most plans to cover without cost sharing all FDA approved contraceptives for women, but currently requires a prescription even when the product or drug is sold over the counter. So for example, for an insurer to cover Plan B emergency contraception, the policy holder needs to have a prescription of some sort and we'll get into what I mean by "some sort" in our discussion. These policies will also matter for coverage of pill. A few states have passed laws that also require fully insured state regulated plans to cover OTC contraception without a prescription. To learn exactly how this works in the wild from January to August of this year, our KFF team went into the weeds. We interviewed key experts from some of the states for plans and even some Medicaid programs are required to provide coverage of OTC contraceptives.

In a few moments, Michelle Long Senior Policy Analyst at KFF will share some of the highlights of what we learned. If you really want to dig into the nitty-gritty details of pharmacy billing practices and other operational issues, I encourage you to read the report where there are many details that we may not be able to cover today. Michelle's presentation will be followed by a panel discussion with key players and experts in pharmacy operation and coverage. After the panel discussion, we have left time to take some questions from the audience. I encourage you to put your questions in the Q&A function at any time during the presentation or discussion. We are fortunate today to be joined by an excellent panel. First, we are joined by Don Downing. Don retired in June, 2023 as clinical

professor at the University of Washington School of Pharmacy and endowed chair of the Institute for Innovative Pharmacy Practice.

He and his colleagues developed the first pharmacists initiated emergency contraception, ongoing contraception and immunization programs in the United States. We're also joined by Dr. Christine Gilroy, who is the Chief Medical Officer at Express Scripts, a major national pharmacy benefit manager. Dr. Gilroy leads their clinical efforts to improve health outcomes and increase affordability for clients and members. She works closely with clients to provide clinical guidance on critical plan design, decisions and solutions to address healthcare's biggest challenges. Finally, we are also joined by Victoria Nichols, who is the project director of Free the Pill, which is the national campaign operated under the auspices of Ibis Reproductive Health. The Free the Pill campaign was developed to support education and public engagement regarding OTC birth control pills in the United States.

Next slide please. Before we get started, a few logistics. The briefing is being recorded and the link to the recording will be posted later today on the KFF website. We have ASL interpretation available. To access it, please click on the globe icon in your Zoom control panel and select American Sign Language. A screen will appear and you'll be able to view the interpreter. As I already mentioned, we have set aside time after the panel discussion for questions and I encourage you to submit questions using the zoom Q&A function. I'll now hand it over to Michelle to share what we learned.

Michelle Long: Great. Thank you Laurie. Next slide please. I'm going to dive right into an overview of our study. The goals of our study were to identify state policies and strategies that have been used in these states to operationalize Medicaid as well as private insurance coverage of over the counter or OTC contraception. We also wanted to highlight the successes as well as the challenges that these stakeholders have been having in order to help inform implementation efforts for coverage of OPill and other OTC contraception going forward. We conducted 35 interviews with nearly 80 experts and key players. As you can see listed below everyone from Centers for Medicare and Medicaid services to health plans and pharmacists and more. We focused our study on seven states that already require private plans or Medicaid to cover OTC contraception without a prescription including Illinois, New Jersey, New York, Oregon, New Mexico, Utah, and Washington as well as national stakeholders. Next slide please.

What made this study a bit challenging is the sheer number and variety of stakeholders involved in coverage without a prescription as well as the many roles that they play. And you can see here the ecosystem of coverage for over

the counter contraception ranging from all of these different players and all of these different roles that they play. And over on that purple box on the right there, you can see how OTC coverage it has been operationalized in general, very broadly through of course a traditional prescription from a doctor or other clinician as well as pharmacist prescribing which states can do to expand a pharmacist's scope of practice. There are a number of different approaches that states can use to do this approach. And then finally, without a traditional prescription. These last two are what our report really digs deep into. So in the interest of time, I won't go into them here, but encourage you to see the details in our report. Next slide please.

What I'm going to share with you is what we learned from these extensive interviews with stakeholders in these states. We had a focus on consumers and how this is working for consumers. Interviewees in the states where OTC coverage is required noted that consumers will generally need to obtain their OTC contraception at the pharmacy counter in order for their insurance to be billed. That's true for both Medicaid and private insurance. We did hear from some health plan interviewees that it is possible to pay for OTC contraception at the regular checkout counter with your other products that you're buying and submit a receipt and request a claim from your plan. But again, this is uncommon.

Interviewees noted that awareness of this benefit is very low in these states among consumers. And I'll get into some of the reasons why shortly. Advocates that we interviewed cited some concerns that actually raising consumer awareness and expectations about this benefit without better operational structures in place could actually generate confusion and frustration. And what they're really pointing to here is the fact, as Laurie alluded to earlier, that state health insurance laws and coverage requirements typically don't apply to all health plans that are offered in a state. And it's likely that a lot of consumers don't know exactly what type of plan they have and whether state coverage laws apply to the plan that they're in.

We also interviewed numerous pharmacists as well as pharmacy leadership, and what we learned from them is that in general... Thank you for moving the slide. There has been little specific outreach about this covered benefit to both pharmacies as well as to pharmacists. And we learned that the billing protocols for OTC contraception really varies widely by specific plan and by Medicaid programs as well, which has led to confusion for some pharmacists in how to actually bill for this.

We heard from pharmacies that they're not typically compensated for submitting claims for non-prescribed contraception, which can actually take several minutes to enter an enrollees insurance information as well as process the insurance. And we learned that pharmacy stocking decisions are shaped by many factors including financial considerations for the pharmacies as well as consumer awareness and demand.

Again, going back to pharmacists prescribing just briefly, pharmacists prescribing laws and policies can facilitate insurance coverage of OTC contraception when it's not possible to bill for it without a prescription. But we learned from pharmacists that this fallback approach does have numerous limitations given the multiple demands on pharmacists and their time. And we heard from pharmacists that there is a lack of or no or low compensation for the time in the service. Next slide please.

We interviewed several health plans, again, a national PBM as well as state insurance departments. And from them we heard that the current system really is designed to reimburse for prescription drugs rather than OTC drugs and systems for covering OTC products, like I mentioned really varies. So this lack of uniformity and billing practices has led to confusion among many key players, not just the pharmacist.

Health plan interviewees reported receiving very few claims for non-prescribed OTC contraception, which again could be due to low consumer as well as pharmacist awareness. So it's not entirely clear what the uptick has been in states where this is an option. We heard that few plans provide information about this covered benefit to enrollees and their enrollee facing materials. Kind of circling back to that low consumer awareness and insurance departments in states with OTC contraceptive coverage cited varied state compliance and enforcement efforts with those laws and finally, health plans and the PBM suggested that quantity limits could be a consideration to control fraud and waste. So we did hear that cost is definitely something that these stakeholders are paying attention to. Next slide please.

We also spoke with state Medicaid programs as well as Medicaid managed care organizations in these states. In general, federal law requires a prescription to cover drugs, even those that are available without a prescription. However, as Laurie mentioned, a few states do use their own state funds without receiving federal matching dollars to pay for OTC contraceptives without a prescription for their Medicaid enrollees. Again, here with Medicaid billing protocols really vary by state and even within state based on, for example, whether it's a traditional fee for service Medicaid or a Medicaid managed care organization.

Most state Medicaid programs also said that they have not recently reviewed claims for non-prescribed OTC contraception or that they don't know how often claims are submitted for it. So like with private insurance, we don't have a super clear sense of how commonly this benefit is being used by enrollees.

CMS, the Centers for Medicare and Medicaid services did say that they're accommodating coverage of OTC contraception and Medicaid by encouraging states to submit state plan amendments or SPAs to cover OTC drugs and products generally. But again, a prescription will still be required for it in order for the state to obtain federal matching funds unless they opt to use state dollars.

Finally, some of the take home messages. Thank you. Some of the take home messages here, we asked interviewees what they're kind of thinking of, what their considerations are for coverage of OPill once that does hit the market as well as other OTC contraceptive products in general. And what we learned from them is that outreach and education to pharmacies, to pharmacists, and of course consumers is really going to be a key factor in implementing coverage without a prescription. Many interviewees stressed the value of having a standardized billing process rather than a kind of patchwork approach in order to facilitate coverage. And pharmacy interviewees mentioned that compensation for pharmacies and pharmacists for the time and the process involved in billing insurance is going to be an important consideration for them.

Interestingly, from health plans, we did learn that some of the current billing approaches that are being used right now for coverage of OTC contraception actually may work for billing OPill without a prescription when that does become available. And finally, many of the interviewees said that without clear federal guidance coverage will continue to depend on state policies and decisions made by health plans and state Medicaid programs. And now I'll turn it back to Laurie for our panelist discussion.

Laurie Sobel: Thank you, Michelle. I invite the panel to turn on your cameras and your microphones please. We'll turn to the panelists for our discussion. Just a reminder to our audience, please use the Q&A function to ask any questions, which we'll address after the panel discussion.

Has the panel joined us?

Michelle Long: Yes.

Laurie Sobel: Okay, thank you. Okay, let's start with Victoria at Free The Pill. You have been busy for many, many years coordinating a coalition of groups that have been prioritizing the FDA's approval of OPill and now coverage. Why do you think this access and coverage are important?

Victoria Nichols: Thanks Laurie and hi everyone. It's really great to be here with you. So yes, I work at Ibis Reproductive Health and we coordinate the Free the Pill Coalition, which is now an over 200 member coalition that's committed to bringing birth control pills over the counter in the United States, ensuring that they're priced affordably, covered by insurance and accessible to people of all ages. The FDA approval of course, was a huge win for our coalition, but we're interested in this being something that benefits the people with the most barriers to access due to systemic inequities in our healthcare system and in our society. And so affordability is a really key piece to ensuring that people have access to birth control, that they'll have access to OPill once it is put on the shelves in early 2024. And so we're really focused on now insurance coverage and an affordable price.

We know that a lot of people, thanks to the ACA, are used to not paying anything for their birth control when it's prescribed, and so we see birth control pills as a key part to reproductive health to just taking care of your wellbeing and they're preventative and so they should be fully covered by insurance in private and public plans. We also know that interest in over-the-counter birth control increases if it's covered by insurance, that's what the data shows as well, and we know that particularly for young people, for people working to make ends meet, this issue of coverage and affordability is really key. So we're really looking for any support, particularly as your report showed from the federal administration around insurance coverage and really ensuring that there's no prescription required for any over-the-counter birth control pills.

Laurie Sobel: Thank you, Victoria. Don, you've been practicing in Washington state, which does require private plans and Medicaid to cover over-the-counter contraception without a prescription. We'd love to hear about your experience as a pharmacist and from your perspective, what do you see as the biggest challenges for insurance and Medicaid coverage for OPill?

Don Downing: Laurie, thanks for asking these important questions. By the way, I was introduced as an academic, which I have proudly been, but I also have owned and operated community pharmacies in my career for 15 years and also opened up and operated tribal healthcare clinic pharmacies for a number of years. So I have a lot of experience in dealing with adjudicating claims, and so I want to make sure people knew that I was bringing that to this conversation.

First of all, as you heard earlier, there are a myriad of rules from a myriad of health plans in each state, thus creating a fractured and notoriously difficult pathway for pharmacists trying to make sure that they can successfully bill for medications and being able to bill for a prescribed or un-prescribed OTC medication comes with its own separate set of complexities. Since government officials have recently been telling the public that contraception, including OPill will be covered by most health plans, I became concerned actually prior to that several years ago, that there might be critical roadblocks for consumers seeking insurance payment for their OTC products.

And I'm only really concerned about speaking to pharmacies if a product is sold in a retail store like a 7-Eleven, that the insurance coverage is another matter entirely because they do not bill insurance plans. So a consumer should expect a seamless purchasing experience, but I've yet to see a seamless mechanism for pharmacies to be able to bill for OTC products. Two years ago I had students in my pharmacy reproductive health group survey local pharmacies in Washington state trying to bill for OTC emergency contraception and found that most pharmacists had to resort to prescribing the contraception in order to get insurance coverage. This means that the consumer who decided themselves to purchase the OTC product now has become a patient and the pharmacist now has become a prescriber with inherent provider liabilities. I don't see this as a pathway for easy access to OTC medications, even though it has worked as a stopgap process in Washington state, I don't think that's what we should be going with in the future. Thank you.

Laurie Sobel: That's really interesting just to hear that an OTC product actually becomes prescribed in that situation, as you said, you have then a patient provider relationship, which many people might not want in this case. Let me bring Dr. Gilroy into the conversation. I imagine Dr. Gilroy, from your role at Express Scripts as well as your prior experience as a clinician serving adolescents needing contraceptive care, you have a deep understanding of the role of clinicians as well as PBMs in this arena. How do you think the availability of an OTC pill will impact access to contraceptives and what do you see as the operational challenges?

Christine Gilroy: Yeah, so as a physician who previously served an adolescent population and having taught contraceptive management to residents and clinicians in multiple specialties over 20 years, it frequently feels more complex than it should be. In my current role, really with the PBM, we've been working on policies and initiatives that really expand access to over-the-counter care and to contraceptive care and having over-the-counter contraceptives is definitely a positive step. I am concerned though that while it removes the barrier of

needing to pay for a physician visit and get a prescription from the physician that just as Don said, then in order to be processed against a pharmacy benefit, it does need to be entered into a system that essentially turns it into a prescription.

Additionally, it requires pulling a licensed pharmacist away from other work that they're doing in the pharmacy, which could be administering vaccines, talking with physicians and counseling patients about other medications, just to spend a couple of minutes entering something into the claim system in order for that to adjudicate. So I think there is a significant opportunity to look at modernizing the claims processing system and create a different category for handling over the counter contraceptives, but also expanding over the counter benefits in other drug categories, specifically enabling access to Narcan and then for low-income senior populations that I've served, pharmacy benefits for over-the-counter Tylenol, proton pump inhibitors are also very important in enabling them to care for themselves.

Laurie Sobel: Thank you, Dr. Gilroy. I'm just wondering, following up to that, what do you see as the role for PBMs in facilitating that change in the system? And can you elaborate a little bit on how PBMs work with plans and pharmacies and how that might affect the coverage decisions?

Christine Gilroy: Yeah, absolutely. I mean, in terms of changing the claims engines, that's advocacy work that can be done. I know Don, you and I had made a connection around the opportunity to really advocate for creating a different category within the claims engines to improve access to over the counters. With respect to administering the pharmacy benefits that our sponsors are asking for, our clients are asking for, we do regularly recommend a benefit design that covers both an Affordable Care Act, a zero copay tier. That would be the statins and other medications of high value and also an Affordable Care Act over the counter benefit, which includes contraceptives, but then also folic acid, aspirin, nicotine replacement. We have these benefit designs built out and offer them, frankly recommend them, to our clients as part of the total benefit package that they share with their patients and members.

We also realize there's a significant opportunity to improve education around those benefits. I think the biggest barrier actually being that people don't readily think to take their pharmacy benefit card and an over-the-counter medication to the pharmacist to make sure that they get the shared copay or the zero copay that their plan sponsor has intentionally designed into their benefit. So really a significant opportunity to improve education for patients.

Another opportunity to improve education for pharmacists because again, state to state health plan, health plan, there is widely varying policies for how to handle these over-the-counter prescriptions. And I think creating a more seamless integrated claim design would help make that easier, better to be able to process for the pharmacist or frankly not even require a licensed pharmacist to be engaged at that point in entering the prescription in to make sure that the patient gets their benefit.

Laurie Sobel: Thank you. Victoria, what do you think has worked best in the states that have rolled out OTC coverage without a prescription in terms of consumer education to let them know about this benefit?

Victoria Nichols: Thanks, Laurie. Yeah, it's a really interesting question. So what we've heard from states is that, first I want to give lots of credits to these kind of first six to eight states depending on how you're counting it. They're truly trailblazers in this and have made a lot of really great progress. But I will say that consumer education has been brought up as one of the really big challenges, particularly for state advocates in states that have OTC coverage policies on the books, and there's a few reasons for that. One is that state laws only cover certain types of plans. So as was noted in the report, individual plans and fully insured employer plans, there's a large group of plans that states don't have authority over. And so when it comes to consumer education, it becomes really challenging to educate consumers on what's covered, what's not covered when a very large percentage of the people in the state don't actually have coverage.

So that becomes a consumer education and marketing challenge within itself. And then the other challenge for states is that particularly in the states that first passed the OTC coverage policies, there's not funding for consumer education within their laws. And so just being consumer education is very expensive and there's a lot of work that needs to be done in order to spread the word about this. And so that's also a challenge for states. So I think the states that can begin incorporating both something about funding for consumer education, support consumer education within their bills is important. And then I know in some states there's information on insurance cards about what type of plan it's, so having that information readily available to consumers is important. It's not something that most people know when they walk into a store or pharmacy.

Laurie Sobel: Thank you. Victoria. Shifting gears a little bit, Don, what do you see as challenges or do you anticipate any challenges with stocking and pricing of OPill at the pharmacy level?

Don Downing: Yeah, thank you for asking a question. I think there are a number of challenges. There always are it seems like, but in terms of stocking, it's critically important that pharmacists stock needed products. And I believe that community pharmacies will not only see the importance of an OTC contraceptive, but I think they will also see significant consumer demand for it. And so I think both of those things are aligned with the stocking. It's also important though that pharmacists' education is very clear that there are no age restrictions on the sales of these products. There's no parental permission required unless things like age and parental permission are imposed in given states. Well, we haven't seen that yet, but I knock on wood, we won't.

But how and where in the pharmacy it might be stocked is an important matter here. A challenge today in today's community, pharmacies, especially in larger chains, is that the decision to stock over the counter products is most frequently in the purview of the store's non pharmacy front end staff. Think of a CVS or a RiteAid or a Kroger pharmacy or something. The front end items in the pharmacy are not controlled by the pharmacist. They're controlled by non pharmacy staff. And so if the front end staff does not stock the product or makes it relatively unavailable because it's behind a locked case or something, I would expect that you would have people coming to the pharmacy for it. The thing is that the pharmacists, even if they order OPill from their drug wholesaler, they're not allowed to stock it over the counter.

They can't put it on shelf space out front. They have to keep it behind the counter. So in terms of a real OTC experience, I think there'll be challenges here because in some cases it may be that the pharmacy has it, but they're not allowed to have it available displayed over the counter. So I think that's going to be a challenge we have to work with. I'm also concerned about pricing historically, depending on the class of trade, unusual term of the purchaser of drugs. For instance, a class of trade might be a Title 10 clinic or a tribal clinic or a government clinic or a class of trade in our case could be a community pharmacy, a chain store, an independent. The cost to purchase medicines between those classes of trade is significantly different. And I have experience with this because they help bring Plan B to market, and I saw this happen.

While community pharmacies are the largest purchaser of medications in the US and they are where the vast majority of consumers buy their OTC and prescription medications, these community pharmacies almost always pay far more for the same medications sold to other class of trade purchasers.

To give you an example, when Plan B did become available, the price point for Title 10 clinics was less than $10 per dose. At the same time, the starting cost to

community pharmacies was over $25 per dose. I'm concerned that if this pricing scheme occurs with OPill that the vast majority of consumers purchasing it will have to pay the highest prices. If OTC billing system is not simplified by the health plans, then low income people wanting OPill will be faced with costs probably beyond their means. And so this pricing model seems inherently unjust. I think we need to address this before this product becomes available. I personally would promote an equal price across all classes of trade and eliminating a lot of their rebate hoopla that occurs, that often elevates the price of drugs. Thank you.

Laurie Sobel: Thank you, Don. I have a final question for all the panelists, and some of you might have already touched on this, but given the information and operational challenges that Michelle presented that we learned from our interviews, and based upon your extensive experience, what do you think needs to happen to facilitate coverage of OPill and other OTC contraceptive products and what do you see as the potential barriers? I know we've touched on some of this already. Let's start with Dr. Gilroy.

Christine Gilroy: Yeah, I think modernization of the claims system is the first one. I think also making sure that, I really appreciated Don's comments about the variability and pricing that's offered to the pharmacies, but also looking at making sure that we're reimbursing pharmacists who in many parts of the United States are core components of the health system is really important. I know this week I was working on policies to actually expand pharmacists reimbursement for injections, not just vaccines, but actually to a list of drugs. And top of that list of drugs is the contraceptive injectable progesterone. So really looking at them and elevating them as components of the health ecosystem where they're serving and not tying them to administrative functions like entering prescriptions into a claims database in order to get the benefit.

Laurie Sobel: Thank you. Victoria?

Victoria Nichols: I'll say two things. One is really leveraging the learnings from state advocates and states that have done it and have experience with the implementation challenges, listen to what they have to say in terms of how to smooth that process, more support for consumer education, some funding for that from the government would be really helpful. And then I think throughout your report, so many people reference just consistency in the guidance from the federal government. It says something in the FAQs that's different from HRSA's guidance and having some consistency there would be really helpful, so everyone's on the same page about what the law is and how to enforce it.

Laurie Sobel: Great. Thank you. And Don, if there's something that you haven't mentioned already?

Don Downing: Yeah, first of all, I appreciate the comments and Dr. Gilroy's comments are spot on, but she represents Express Scripts, but there are other pharmacy benefit management companies in many health plans that she may not be able to speak for. So I really believe that a nationally accepted claim processing system needs to come to be. There isn't one right now, as you've heard. There are many, many different ones. One of the things that pharmacies already have to do if they're going to run a claim through is put a prescriber/provider in there and a national uniform dummy provider number that signifies it's an over the counter contraceptive would be very useful so that everybody in every state, and hopefully we get adoption by all the health plans of this, would be very useful in streamlining this process.

Laurie Sobel: Well, that falls very nicely into the first question we have from the audience. I'll invite Michelle to join us for the Q&A. And again, anybody who has not already put a question into the Q&A function, feel free to know. We have quite a few questions already lined up. And the first question really goes to what Don was just talking about, asking can you clarify the difference between difference pharmacist prescribing and a standing order? And I might add to that a dummy NPI since you just mentioned that, to achieve OTC contraceptive coverage.

Don Downing: Well, so Washington State does not have a standing order for contraception. We prescribe in Washington state, and that has served us well in our state. We were the largest prescriber of Plan B when it was prescription only in the entire country. So that system can work, but in states that don't have that standing order scan-

Laurie Sobel: Can you just clarify what a standing order is?

Don Downing: Yeah, so a standing order is typically a state government makes the decision whether a legislature or a health department signifies that a pharmacist is actually not prescribing, but just fulfilling. California, by the way, has this, is fulfilling a pre-authorization by the government to provide a product. So upon request, a pharmacist can follow the standing order and fulfill that order and dispense it. Prescribing is different in that it infers that there's been a clinical intervention by the pharmacist or anybody who prescribes physician, nurse practitioners and they accept that they have done their due diligence in making sure that the product they're prescribing is safe and effective. That inherently adds liability, and this is why I think we need some other system.

Laurie Sobel: And just to clarify, the pharmacist prescribing actually takes the pharmacist time whereas the standing order does not. Is that correct?

Don Downing: Not only time, but responsibility, personal liability, yes.

Laurie Sobel: Okay. So the next question is for everyone. Do you think there are any lessons learned from coverage of OTC COVID tests that can be applied to OTC contraception? Does anyone want to start with that one?

Don Downing: Well, I'm probably the one who is the most tuned into that. So I surveyed a number of pharmacists in Washington State about how that COVID billing went. Most of the time, their eyes rolled back in the back of their heads. They said it was complex and very difficult to navigate, and some pharmacists just didn't even bother to bill because they just couldn't figure it out. Again, not a uniform system, and although it looked like it might be helped that it happened very quickly in uniform building processes, there was not time to develop that in a way that made it useful.

Laurie Sobel: Okay, thank you. Dr. Gilroy, there's a question about online sales and online retailers and also how would this work with contraception apps. Do you have anything to add there? Just to answer that question, how this would work with online retailers as well as tele contraception?

Christine Gilroy: Yes, so I think it's a similar process. In order to partner with making sure that the tele prescriber and the online retail pharmacy are using the pharmacy benefit to make sure that the patient gets the lower copay that's available or the zero copay that's available is an important point of coordination. I did hear as part of this work that there were some potential barriers with using online retail pharmacies that they were only dispensing or only willing to dispense 90 days at a time. And I do think it's very important to preserve a wide spectrum of time dispensing from 30 days through 12 months just to be able to make sure that people have consistent access or that we're meeting the price that they have available to them.

If they don't have a zero copay benefit available to them and they can only pull together the money for one month's copay at a time, they need to be able to get that as well. So I think flexibility from online retail pharmacies in partnering with pharmacy benefits, it should actually be easy and more seamless for us to do the claims adjudication there. And then also making sure that they are flexible with the quantities dispensed as well is important.

Laurie Sobel: That's a good point about the quantity. We hadn't really talked about that before. There's a few questions about states that don't currently have legislation and whether you think that any state considering new legislation should include language that creates a streamlined claim system and whether you think that's possible. And then also a separate question that's related about what advice you would give to state legislators. We know that this is a bipartisan issue in terms of getting contraceptive access, and so what advice would you have for including things in a new state law? Victoria, do you want to start with that one?

Victoria Nichols: Sure. I think that I'll maybe let Don handle the claim systems and also Dr. Christine provide advice on that, but I think for any new bills coming into different states, again, I mentioned before providing some information on consumer education is something that was missing previously. I think that adding some information about claims might be helpful, but if we don't get some consistency across states from a federal level, I feel like it's just going to further complicate the landscape overall. But I'll leave it to the pharmacist to comment on that.

Don Downing: Well, I would like to comment on that. First of all, a pharmacist being able to prescribe as we do in Washington since 1979, has created access points that are pretty phenomenal. Witness are prescribing of emergency contraception. To Dr. Gilroy's point, we also need to be able to prescribe for more than one month at a time. Unlike emergency contraception, OPill will be a month after month after month product, and if somebody has to go in every month, that's going to have a chilling effect on adherence to therapy. So 3, 6, 12 months is critically important. And I just want to agree with Victoria's comment. I think if each state goes in and does their own thing in their own way, that the consumer experience by just crossing a state line could be entirely different and expectations are not going to be met, and we need a uniform federal standard here.

Laurie Sobel: Thank you. We have a question that goes back to the pricing question and just do you have any thoughts on how the OTC contraceptive pill such as OPill or something that might become available in the future might be available for people who are uninsured? Does anybody want to take that one?

Don Downing: Well, I've had a lot of experience with that given the fact that we've had this two-tiered system with the easiest accessible access to over the counter contraception is through a community pharmacy, and yet they're the highest price, and that's likely to also be the case in a retail store like a 7-Eleven again, for example. They're not going to be a preferred trade client. They're going to

be paying a lot more for it, and that really has a chilling effect on low income people able to access.

Consequently, with this two tiered system, I developed schemes in several states where community pharmacies borrowed inexpensive or no cost contraception from Title 10 clinics and kept it in a separate bin where it's legal in various states to be able to hand out to people who couldn't afford to pay for it. It seems an unnecessary burden on pharmacies to have to keep a double stock. Why couldn't we all have the same price that would make it affordable? And for people who don't have insurance and have no cash, I found pharmacists routinely being pretty generous about finding a way to make that available to them without cost, but they can't do that for everybody because they won't stay in business.

Laurie Sobel: That makes sense.

Christine Gilroy: If I could just double down on that, that is incredibly important to be able to get to a more consistent pricing across those sites. Even in one of my prior practice environments was a children's hospital that was serving uninsured Medicaid and insured populations. We actually had in our clinic three different separate stocks of contraceptives that depending on the patient's situation, we had to make documentation to dispense from. So it is quite complicated at the provider level, whether you're a pharmacist or a physician who's providing that care.

Laurie Sobel: I see. Yeah, that seems like a lot to have three different stocks. Following up on the uninsured, can we talk a little bit more about Medicaid and how this has worked for Medicaid patients? We know from the federal government that there's a requirement for a prescription and we know that there's been some workarounds. Don, do you want to just start with talking about how you were able to bill for Medicaid patients? I know Washington State used their own money for this, but just how that worked.

Don Downing: Yeah. We began a scheme in the mid 1990s, even before Plan B became available because pharmacists were prescribing a Yuzpe regimen, emergency contraception in large numbers. In order to get Medicaid to cover it, we had to have a prescriber ID number. And in those days you used DEA numbers, which was supplanted by what's now called NPI numbers. So today is NPI numbers. So in Washington state to this date, Medicaid and Medicaid managed care plans frequently still use the same dummy NPI number, DEA number that several of us conceived of many years ago. And so it does allow transactions to occur, but it is something that, again, since NPI numbers are assigned by CMS, Centers for

Medicare, Medicaid, it's a federal government really initiative whether they would allow this uniform NPI number, and so we need to make sure that we find a pathway there.

We also use store NPI number, so a medical clinic or a pharmacy also have their business NPI number. The thing is that that says that the store prescribed it. Stores and medical clinics without their clinicians don't prescribe. Their clinicians do, and they use their own NPI number. So we see some insurance plans will accept a store NPI number. That means they have to have those store numbers on file where the claims are adjudicated. If they don't have them on file, then the claims won't go through. Then finally, we get Medicaid claims to go through by pharmacists prescribing the contraception as a provider to a patient rather than a consumer asking to have their decision adjudicated without a provider being involved. By the way, every time we adjudicate claims, of course, patients run the risk of having an explanation of benefits coming out to parties that they may not want to see access to. So we developed a scheme to suppress those explanation of benefits going to parents of unemancipated youth, and there are a lot of complexities to this in order to make

Laurie Sobel: That could be a whole other webinar just about EOB suppression.

Don Downing: Yeah, yeah, yeah. Thanks.

Laurie Sobel: Can you clarify the states that do use their own state money for the Medicaid coverage, they then don't receive the federal reimbursement, and did they also lose the Medicaid drug rebate in those instances?

Don Downing: I know that there are no cost sharing between Medicare and the state, so my state has sent a lot of money covering what Medicare, the federal government would normally cover. I don't know about the rebate.

Laurie Sobel: Okay. And Victoria, can you just comment on why the Medicaid piece of it might be so important to people who are on Medicaid?

Victoria Nichols: Yeah, so Medicaid is a program that serves people with lower incomes. And so if we don't have a system to serve that population, that's population that if we're thinking about this as an equity issue, would benefit the most from having access without having to jump through all the hoops. And so I think thinking about this from both an economic justice issue and a reproductive justice issue, really wanting to ensure that the consumer experience also is as seamless as possible for the Medicaid population and any population that has more of a challenge paying for this out of pocket.

One other thing just to add, and Michelle, I know you're much more familiar with this data, but I believe in the 2022 KFF survey, it focused on the uninsured population as well, and that that group of folks in the survey were willing to pay more than some other groups. And Michelle, happy to have you talk more about this, but you're really comparing the cost of paying out of pocket for something on the shelf versus going and getting a prescription with a provider, which can be much more costly if you don't have insurance. So just wanted to raise that as we're talking about the barrier around cost.

Michelle Long: Yeah, Victoria, I think you said it well. We did find in our 2022 Women's Health Survey that uninsured women on average were more likely than women with insurance to say that the reason they were interested in using an OTC oral contraceptive pill is because they thought it would save them money, which Victoria, as you said, definitely probably reflects the fact that they would no longer need to pay perhaps out of pocket to make a doctor's appointment to get that prescription. And then of course, as you mentioned, that they are a little bit more likely than those with health insurance or Medicaid to say that they would pay a little bit more per month for those pills.

Laurie Sobel: Thank you. Well, we've discussed a lot about systems and state roles, and we've alluded to the federal role, but I just want to make sure that we get everyone's perspective about what do you think the federal role here might be, both within terms of private insurance coverage as well as Medicaid? Dr. Gilroy, do you want to start with that one?

Christine Gilroy: Sure. So federal policies we're open to conversation about how federal policies could really expand access to care in a way that wouldn't also create additional costs. I think that the response to the COVID pandemic actually illustrates ways that we were able to kind of get past barriers that were tied to reimbursement pathways in the federal government through CMS Medicaid/Medicare services in order to get to really a new platform for delivering healthcare, elevating pharmacists, elevating virtual health and telehealth as important components. So we're very open to that. I do think the issues with Medicaid being a state to state benefit, I think there are some core federal policies that could help modernize that benefit, modernize access to the benefit, especially for a growing pool of over the counter medications, contraceptives that we're talking about today, but also Narcan, and then think about the other medications.

So I know we have programs to enable access to folic acid for women in disadvantaged parts of the United States specifically because that OTC benefit is so difficult to process. So certainly very interested in how we can move forward with federal policies. I would like to see for physician prescribed contraceptives,

the ability to move them to the orange list, the list where pharmacists can also do interchangeability for those prescriptions. It's actually very difficult for physicians to remember the six different names tied to a given oral contraceptive pill. I think that would be another opportunity for policy modernization that would benefit patients and physicians and pharmacists across the board.

Laurie Sobel: Victoria, I know you have already told us that you think there should be federal policy, if you can elaborate on that a little bit more.

Victoria Nichols: Sure. Yeah. Our biggest focus is around the ACA and ensuring that it's clarified that a prescription is not required for coverage. When thinking about over-the-counter products in general, even I was reflecting on the COVID experience as well. I never submitted my receipts for reimbursement and never got that money back. I don't know where the receipts are now. And so if you're requiring any additional step for the consumer, that's another barrier. I have a lot of privilege just thinking about people who don't have that to have to go through additional steps to either get a prescription for something that's over the counter or submit any type of receipts. It's really unnecessary and I'm sure there's a solution that we can come up with to make the consumer experience as seamless as possible and to cover this really important reproductive health product for everyone who wants and needs it.

Laurie Sobel: Thank you. And Don, you alluded earlier to a dummy NPI number at the federal level. If you can elaborate a little bit about that and talk about any other role you see for the federal government.

Don Downing: Well, again, the NPI number comes out of CMS centers for Medicare, Medicaid. Historically, decisions by Medicare on an insurance structures and such have been adopted by the commercial plans throughout the country. So it seems like it's really important to get CMS on board with standardization, not only regarding billing design, but also questions of I'm thinking LGBT community where a person without a uterus, maybe a male like me going in and purchasing an OTC OPill product, are they going to be denied the sale, the billing? Those questions need to be nationwide because states variations are going to have a dramatic impact on the consumer experience otherwise.

Laurie Sobel: Right. I think we have time for one more question. This is really about whether there's any possibility to get coverage of OTC drugs outside of the traditional claim system and whether anything about that came up in our study or if Victoria has any information about that. So essentially, could you go to a place

that doesn't have a pharmacy at the back of the store and somehow get coverage? Michelle and Victoria, do you want to address that?

Victoria Nichols: Michelle, you can go first.

Michelle Long: No, you go first.

Victoria Nichols: So the hope is yes, we don't currently have a system set up for that, so we would like to see this in non pharmacy retail environments and have people be able to get it covered by their insurance. The mechanism for that is not there right now, and it's not seamless for the consumer, but the long-term goal is for us to figure that out. I'm working with Don and many others in our coalition to try to figure out solutions for that, that don't require a lot of steps for the consumer, but as of now, there's not a clear mechanism for doing that, but hopefully in the future.

Michelle Long: Yeah, I think Victoria summed it up. I would also add that in addition to the systems just not being there for a cashier, say at a 7-Eleven to be able to get into bill somebody's insurance right from that cash register, I think that there would also be some issues around privacy and HIPAA and what kind of personal information a cashier at 7-Eleven would be able to have.

Laurie Sobel: Great. Thank you. Well, unfortunately that's all we have time for. I want to thank our panel for a very insightful discussion. I want to remind everybody the recording of this event will be posted on the KFF website later today, and all registrants will be emailed a link to the recording when it's available. There is a lot more detailed information in the report. We just got to the tip of the iceberg today about how insurance coverage has been operationalized in the remaining challenges.

If you want to dig deeper into all these issues involved, we also just published a new issue brief that provides additional background on OTC contraception. Both the issue brief and the report can be found on kff.org. We thank you all for attending and look forward to a continued dialogue about these issues. Enjoy the rest of your day.