Patient Power

Ask Aimed Alliance: Guide to Cancer Care Access Bills in Legislature(s)

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Andrew Schorr:
Hello and welcome to Patient Power. I'm Andrew Schorr in Southern California near San Diego, and we're back with another of our Aimed Alliance programs produced by Patient Power, the ABCs of Patient Power. And joining us—the staff attorney from Aimed Alliance in Washington, D.C. and that is John Wylam. John, thanks for being with us.

John Wylam:
Oh, thank you, Andrew, pleasure to be here.

Andrew Schorr:
Okay, John. In Washington, you monitor what's going on with government agencies that affect all of us with health, and particularly those of us like myself and our viewers with cancer. We're dealing with regulations and often a lot of expense. So, what's going on with agencies matters at the federal level and the state levels. So, we're gonna talk about that in our program. Let's start with CMS or Medicare and Medicaid. There are some things going on there help us understand what could be significant for us.

John Wylam:
Of course. So, the federal government has been very busy lately proposing regulations that could impact patient access to care. I'm gonna give you a brief overview of two of them that I think are most relevant. First up is the Six Protected Classes proposed rule and this was proposed in November 2018. So, this proposed rule is to provide greater flexibility to Medicare Part D and Medicare Advantage Plans to manage the medications that are in the six protected classes. And what are those? The six protected classes are special types of medications that the government determined should be broadly covered. Medicare Part D Plans have historically been required to cover all, or substantially all, medications in each protected class. So, this proposal was issued to save the government money and to improve the ability for plans to negotiate with pharmaceutical manufacturers.

So, importantly for cancer, one of the protected classes is antineoplastics, better known as chemotherapy treatments, which are used to treat cancer specifically. If this proposed rule is finalized, Medicare Part D and Medicare Advantage Plans can subject these medications to step therapy and prior authorization. So, this could threaten patient access to care by creating additional barriers between patients and the medications that they need.

In the context of cancer care specifically, this policy proposal is problematic for patients because it assumes the cancer medications are freely interchangeable and most of them aren't. Newer cancer medications are targeted towards specific mutations of cancer and would likely be ineffective at treating other types. So, requiring a patient to try and fail on other medications before being allowed to access the one they were originally prescribed could result in care delays, and as you

know, cancer is a progressive condition. So, when you're dealing with care delays, in that time, a patient's cancer could progress and that could lead to poor health outcomes and increased costs on the healthcare system...

Andrew Schorr:
...right, and I'm just gonna comment on that in a second. So, what you're saying is, it could give more leeway to these insurance companies or the policies here, so that I might get a therapy that my doctor and I know probably wouldn't be effective for me, and it might be debilitated by that therapy and delayed in getting to what my doctor suggests might be more targeted for me and effective?

John Wylam:
Absolutely. That's exactly what could happen. And in some cases, you might be eligible for an exception where you can override that step therapy protocol, but even in that situation, you and your provider are gonna have to take the time to complete that paperwork and have the request decided by the insurer. And even that by itself is gonna be a care delay. So, it seems like a lose-lose no matter what.

Andrew Schorr:
Okay, so that's one for Medicare that they announced in the fall of last year. What about something else?

John Wylam:
Yeah, so this isn't quite a regulation but it's equivalent to one. It's the step therapy in Medicare Advantage guidance that was issued by CMS in August of 2018. So, there was original guidance that was released in 2012 that had prohibited outright Medicare Advantage Plans from using step therapy as a utilization management technique.

So, the guidance that CMS issued last August rescinds that guidance from 2012 and that is gonna allow Medicare Advantage Plans to use step therapy; and that's specifically for medications available through Medicare Part B. Part B medications are usually administered directly by a provider in an office or hospital setting. CMS issued this guidance, again, to save money and improve the ability for Medicare Advantage Plans to negotiate with pharmaceutical manufacturers so...

Andrew Schorr:
...okay, so it's the same kind of thing we were talking about a minute ago related to step therapy is, you might get blasted with an old chemo that your doctor knows wouldn't be right for you, it might be toxic, rather than perhaps a more targeted, more refined therapy that might be right for your condition, and you could get sicker in the process, as you said, cancer, progressive condition, maybe be very debilitated, or quite frankly, some people during that process could pass away? How tragic.

John Wylam:
That is correct. So, the one difference between these two, though, is that the previous rule did specifically deal with those six protected classes, so this change wouldn't apply to chemotherapy drugs, but it could apply to other drugs that patients are prescribed to treat their cancer or their associated symptoms. So, either way, there's gonna be a lot more step therapy happening in these types of plans.

Andrew Schorr:
All right, okay. That's at the federal level. Now, Congress is also trying to work on this, and I know, for instance, with the Affordable Care Act, there was money taken away from raising awareness of it for people to be recruited, to know, and there is legislation pending to try to restore that, right?

John Wylam:
That's correct. So, we refer to that as ACA outreach and enrollment funding, and the Trump administration had slashed that funding last year. And so, that's not ideal, because we need this funding to help the state exchanges enroll people in health plans. And when you're dealing with health insurance, the more people you have enrolled in a health plan that usually means that the cost is going to be cheaper for all the enrolled in these.

So, when you're taking this money away and you're preventing people from signing up, what you're doing is actually increasing the cost for everybody else. And so, we're paying very close attention to this. So, we're hopeful that some legislation can make it across the finish line that restores that funding.

Andrew Schorr:
Okay now, there's something else going on, too. There have been some of these association plans, which I don't—maybe you could explain it. But the concern was, would this again siphon off people from the ACA, right?

John Wylam:
Correct. So, it's the same concern, and these are just different types of plans. So, the Trump administration has taken a regulatory action over the past couple of years to expand access to and the availability of association health plans and short-term plans. So, an association health plan is usually formed by bringing together a lot of smaller employers who don't necessarily have the number of employees themselves to require them to have their own insurance plan.

They're not a larger corporation like other organizations so they'll branch together in what are called "associations" and they'll negotiate together on the health plan that they're gonna offer their employees. And so, what the Trump administration did is that they made these plans more available to consumers, they loosened the restrictions on them. And the reason that's troublesome is that these plans sort of exist outside of the Affordable Care Act, and they're not required to cover all of the same benefits that ACA plans are required to cover.

So, a consumer could unknowingly enroll in one of these plans and think that they have comprehensive coverage, and it turns out that they don't. So, there's a lawsuit going on to decide the validity of these plans and the regulations that enable them. And just recently, a district court judge, John Bates, struck down a federal regulation to allow for the expansion of association health plans, and that's kind of left states wondering about what the legal status is of those plans moving forward. And just earlier this week, the Department of Labor appealed that decision. And so, we're watching very closely to see how that's resolved. On the short-term plan piece...

Andrew Schorr:
...go ahead.

John Wylam:
For the short-term plan piece, it's a similar issue, but Congress is trying to resolve that with legislation instead a lawsuit. So, it's just dealing with the different political dynamic.

Andrew Schorr:
Let's talk about the states. So, some states are working hard to provide greater access for patients and patients like me, cancer patients. And in other cases, they're making more difficult. Maybe you could describe that.

John Wylam:
Yeah, so we've seen a lot of activity in the states this year, and many are wrapping up their legislative sessions. So, in the past month or two, we've seen a number of new laws enacted. Here at Aimed Alliance, we track legislation on a range of access-to-care topics including step therapy, prior authorization, non-medical switching, and co-pay accumulators. I can give you a brief overview of where things stand on these topics. On step therapy, new laws have recently been enacted in Georgia, Oklahoma and Virginia.

One additional bill has passed the Washington legislature, and it's awaiting the governor's signature. So, these new laws will place stronger guardrails on step therapy protocols to protect patients. Without laws like these, patients will not able to override a step therapy protocol, even if the medication they need is medically necessary. On prior authorization, new laws were enacted in Kentucky, Utah, and New Mexico in March. These new laws will more strictly regulate when prior authorizations will be used and how insurers will handle prior authorization requests.

So, great news to share is that Arizona, Virginia, and West Virginia have become the first states to regulate co-pay accumulator programs. So, co-pay accumulators threaten patient access to care by preventing cost sharing amounts from being counted towards their deductible and their maximum out-of-pocket costs when a third party pays the cost sharing amount on their behalf. And so, what this does is it slows the pace at which enrollees can complete the deductible phase of their coverage, and it delays their entry into the coverage phase. So, the laws that are recently enacted in these states will completely prevent that situation from occurring.

Andrew Schorr:
Right. Let me just comment on that for a second, John. Your colleague Stacey Worthy and I have talked about that, and we have another program specifically on co-pay accumulators. But the way I see it as a patient is the insurance companies kind of moving the goal post on you, where you thought that your out-of-pocket cap for medication, for example, or healthcare coverage was X and you said, "Oh, I'll afford that if I need to a year." And then they say, "Well, if you're getting assistance from a drug company's co-pay guard or a foundation that's helping you with your co-pay, it doesn't count towards that." Sounds terrible.

John Wylam:
Yeah, and what's particularly difficult about those is that the programs aren't really communicated to enrollees very well, so people are really blindsided when people find out they may have paid $0 towards their deductible when they thought they'd already completed it, and that can stick them with unavoidable health costs.

Andrew Schorr:
Okay, anything else at the state level that you want our viewers to know about?

John Wylam:
So, those are the highlights that I wanted to provide. I know that I mentioned non-medical switching earlier, but I'm unfortunately unable to share any progress on that this year, so—hopefully next year.

It's similar to that. It's more like, when you're enrolled in a health plan, and when you enrolled in that health plan, you knew that a certain drug was gonna be covered on a certain tier. And then, you get halfway through the year, and suddenly your insurer decides, "We're changing the coverage status of this drug. We're no longer gonna cover it." So, what happens is it's a mid-year switch of your formulary at a time when you're unable to go find other coverage, so for some people, they could be completely cut off of the medication that they're stable on.

Andrew Schorr:
I hope we can talk another Jon about that progress there. So, as we get to the close of our program then, our viewers and I'm saying, "What can we do, John?" So, how do we tell Medicare or a Congressman, "Hey, this affects us and we care and please help us we access to the medicines we need and deserve in a financially affordable way," or at the state level, what do we do?

John Wylam:
Of course. So, you can always get more involved. These issues are prevalent in every state, and if you're passionate about them, you can get engaged with your state-elected and federal representatives to make your voice heard by sharing your story. Some issues may only be handled by state legislators, while others are exclusively handled by Congress or a regulatory agency. So, you might need to do some light research to figure out who the appropriate policymakers are before reaching out to anyone directly.

But also, state and federal legislators often hold hearings when they're considering these issues, so you can do some research to find if your state will be holding a hearing on a topic you are passionate about in the near future, and you can work with the members of the committee that are holding that hearing. You may be permitted to testify before the committee to support or oppose legislation that they're considering. But more than that, state and national patient advocacy organizations often have great connections with legislators, and they may be able to help you in this regard. So, it could be helpful to find an advocacy organization that aligns with your values and start working with them on these issues. And if you're unable to attend a hearing in person, you can always write a letter to the members of a committee. You can also write letters to legislators who are not even on that committee to urge them to support or oppose legislation when it comes to a full floor vote. So, also, don't just assume your voice and your vote don't count.

In my previous life as a lobbyist, I personally heard from congressional offices that they sometimes have to hand count how many people actually call in to support or oppose a specific issue, and the member's vote isn't decided until the moment their vote is cast. So, you could be the deciding factor for your member of Congress. You can have an even greater impact on the state level where your unique perspective could really make a difference. So, to stay ahead of things you'll need to pay close attention to current developments in Congress as well as your state's legislature.

To stay up-to-date on activities of your state's legislature I'd recommend subscribing to a local political publication that reports on legislation matters. If you know that a specific legislative committee will handle matters that you're passionate about, you can likely subscribe to updates from that committee to receive notice whenever hearings are scheduled. And considering subscribing to a national publication as well. I often rely on these to provide easily digestible summaries and developments currently before Congress and many other federal regulatory agencies.

So, I'd recommend Kaiser Health News, Health Affairs, and the Commonwealth Fund among others, as good examples of reputable sources I often rely on. And they will often issue reporting on state issues as well, so… I just wanna wrap up by saying that, also, if you're interested in the issues that we work on, you can visit our website at aimedalliance.org and you can also subscribe to our newsletter where we provide monthly updates on these issues.

Andrew Schorr:
Okay, and we'll put all that on the screen and we'll continue our dialogue with our viewers about all of this. John Wylam from the Aimed Alliance, staff attorney there with your—really taking the temperature of what's going on in the states and the federal government. Thank for looking out for us, John. And we'll continue our discussions with our "ABCs" program. Also, I just wanna mention, John, just briefly a big other issue going on is keeping our health information private.

There's been a lot of work on that in Europe and that's other discussion in the U.S. So, John, we'll have another program with the Aimed Alliance specifically to talk about protecting our privacy of our health information.

John Wylam:
Looking forward to it. Thank you for—having me here.

Andrew Schorr:
Thank you for being with us. I'm Andrew Schorr, thanks to the Aimed Alliance and our partnership with them. And as I like to say, remember, knowledge can be the best medicine of all.