PUBLIC ACT 20-4 DIABETES AND HIGH DEDUCTIBLE HEALTH PLANS

WORKING GROUP

March 19, 2021

Convened by the State of Connecticut, Department of Social Services, via Microsoft Teams

Members joining via Teams: Bradley Richards (Chair), Christopher McClure, Laura Nally, Marjorie Lazarre, Tizita Fekredengle, Monica Jensen, Anthony Yoder, Kara Lewis, Suzanne Lagarde, and Sue Veer. Dave Rackliff observed the meeting but was not able to participate due to a technical issue.

DSS Staff joining via Teams: Herman Kranc, Manager, Integrated Healthcare/Pharmacy, and Trish McCooey, Staff Attorney

Members of the public observed the meeting via Teams.

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Call to Order, Introductions and Approval of Minutes

The meeting was called to order at 9:03 am by the Chair, Bradley Richards, M.D.

Dr. Richards welcomed new member Christopher McClure, who was appointed to the Working Group by Secretary Melissa McCaw, Office of Policy and Management. Chris handles legislative matters for OPM and has had Type 1 diabetes for more than 30 years.

Sue Veer moved to approve the Minutes of the March 4, 2021 meeting. Suzanne Lagarde seconded the motion. Motion carried unanimously.

1115 Waivers

Trish McCooey briefly described Medicaid 1115 waivers. She stated that there are two core features of such waivers: 1) they must further the purposes of the Medicaid program and 2) they must be cost neutral to the federal government. While they are flexible and intended to allow states to experiment, she did not come across any 1115 waivers that performed or allowed for services comparable to the 340B referral program contemplated in Public Act 20-4. Although the statute allows the DSS Commissioner to proposed an 1115 waiver as an alternative if the Working Group recommends that DSS not proceed with the referral process, there is no clear path by which an 1115 waiver would allow for members of the public who are not eligible for Medicaid to access low cost drugs. The approach to 1115 may very under different federal administrations. The current federal administration is looking at 1115 waivers that had been approved previously, including work requirements for Medicaid beneficiaries.

Review of Other States' Approaches to Insulin Drug Cost Containment

Sue Veer reported on her research on other states' approaches to insulin cost containment. She did not find any state that was using the exact mechanism proposed in Public Act 20-4, that is, a process to refer diabetes patients to a state agency to make referrals to 340B covered entities for diabetic care. She noted that some years ago West Virginia had conducted a demonstration in which FQHCs acted as a preferred provider for prescription drugs for certain populations. She also noted that there are local projects such as Independent Practice Association models that negotiate with managed care payors for health care costs for patients. Also, as touched upon during the last meeting's discussion, she again saw two potential barriers to a program based upon referrals to FQHCs: 1) centers' capacity and 2) identification of the 340B claim. A referral program that increases 340B usage and claims from FQHC is likely to meet resistance from the Pharmacy Benefit Managers (PBMs) that do not want to experience financial losses from the processes. She reported on some efforts to protect 340B covered entities from disparate treatment once a claim has been identified as a 340B claim. She cautioned against establishing a referral program that would result in lower or decreased resources for the FQHCs.

Review of Public Act 20-4 Requirements:

Dr. Richards asked the Working Group to give their overall views on the value or viability of the referral process as described in the statute, before taking a formal vote on whether to endorse the concept.

Dr. Yoder emphasized that 340B provides a viable and great service to many patients, but the emphasis must remain on the patient's status as an FQHC/Covered entity patient. The drugs may not be dispensed by an entity when the related medical services are being provided elsewhere. It would require an expansion of the scope of services, which is outside of the Working Group's charge. Sue Veer agreed that it is very clear that patients may not use 340B entities to fill prescriptions, without receiving the related care.

Dr. Lagarde stated that it is difficult to answer the question on a referral process posed by the legislation when the Working Group does not know what the referral process is intended to be. If a patient is diabetic, with high copayments for their insulin, but is very satisfied with their current provider, it would be essential for an FQHC being referred this patient to ensure that they become the FQHC's patient. That appears to be a critical sticking point. Sue Veer said it was unclear what criteria would be used for the referral. Would the patient be required to be seen at the FQHC at prescribed intervals (e.g., every two years). Marjorie Lazarre agreed that a variety of issues suggest that the Working Group should vote against establishing the referral process.

Ms. Fekredengle added because most FQHCs operate under a contracted pharmacy model, there are risks with the prescription being presented but not accepted as a 340B prescription. Further, PBMs are imposing restrictions on 340B prescriptions, sometimes resulting in rejection of a 340B claim one to three months after the prescription was first presented, causing pharmacy reluctance to participate. As a DSH hospital/340B entity, she agrees with other Working Group members concerns about the increasing restrictions on covered entities. In the acute care setting, the proposed referral process presents challenges in terms of patient choice, the existing/natural intersection between the diagnosis and providers involved.

Dr. Richards noted that there was a very open question as to how the referred individuals would come to DSS, whether by a third party or the likelihood that they would find DSS on their own.

Ms. Nally asked how much o the care would the CE need to undertake, for example, could they see a PCP at an FQHC, but consult with an Endocrinologist for dosage. Dr. Yoder agreed that he does that for some patients, but it can entail a great deal of effort.

Sue Veer mentioned the concept of an Independent Practice Association, a statewide entity that serves as a coordination structure for referral and would have the ability to negotiate with payors.

Ms. Nally noted that there are some solid sources for information already in the diabetes community, such as insulin 4 all and the JDRF that provide referrals to other resources, raising the question as to whether another referral organization or layer is needed. Dr. Richards asked whether another layer in the process or step would be useful for patients. Also, how can the patients who do not use social media be identified and assisted with referral.

Dr. Lagarde said the idea of "referral" to FQHCs, to the extent is suggests the clinics are a source of cheap drugs sends the wrong message. Instead, the FQHCs should be viewed and presented as a source of comprehensive, high quality care.

Ms. Lazarre noted that maybe part of the calculation is whether fear and/or pressure from the manufacturer would interfere with the referral process, allow it to be sustainable or could create a crisis. If all private pay patients were transferred to 340B there could be price pressures that 340B entities could not fully control.

Dr. Richards reflected to the group that there appeared to be a consensus that a referral process as proposed in the bill raised a number of concerns. He added that state funding would be an additional issue, as there are no funds identified in the bill.

Sue Veer also mentioned concerns re sustainability. Contract model is becoming increasing difficult, forcing more and more covered entities to look to owning their own pharmacies. In Virginia, for example a group of FQHCs purchased an elementary school for purposes of establishing a mail order pharmacy to serve different populations, including patients with diabetes.

Marjorie noted some of the difficulties in mapping out the potential referral process, including their point of entry to diabetes care and when and where they encounter difficulty with the cost of the drugs. It would require cooperation/assistance of providers/prescribers and a great deal of proactive work. She added that some messaging to prescribers could be conveyed via electronic medical records/as part of e-prescribing.

Dr. Richards turned the discussion to how the referral process would assist persons with diabetes.

Ms. Lazarre noted that to assist patients, the whole process would need to be transparent - i.e., providers would need to know up front that it could entail a change in their current provider? This creates an inherently difficult conversation and dynamic of the provider sending someone out to provide the care they had been providing

Ms. Fekredengle asked about the role of the State of Connecticut as a 340B provider Trish McCooey mentioned that 340B covered entity types include TB programs, STD, AIDS drug assistance programs, but the State itself does not qualify as a covered entity and the Medicaid agency does not.

Ms. Nally noted that the 340B is only one tool to help patients and it cannot help patients with all the needs related to their diabetes care. Specifically, for many patients, diabetes equipment (pumps, devices) is a significant cost that may not be covered (or adequately covered) under their health coverage.

Sue Veer noted that the discussion suggests that a state level care coordinator and patient assistance program to help with a variety of options might be more helpful than the referral process.

Laura Nally noted that an existing website will take you through many the options already. She noted that the Alex Smith legislation in Minnesota, which allows for emergency insulin supplies at the pharmacy and requires insulin manufacturers to participate is currently being challenged in court.

Sue Veer noted that a human level of assistance, such as that provided by FQHCs, including their community health workers, is an essential adjunct to those websites and resources. Dr. Yoder agreed that there is a subset of diabetes patients who are not skilled at navigating the existing resources.

Ms. Lewis emphasized that pharmacists have become less able to assist with this type of information and referral over the past several years due to increasing demands on their time. Ms. Lazarre concurred that community pharmacists and staff have much less time to assist patients with

Ms. Nally emphasized that her organization in the original legislation – Senate Bill 1, had been seeking more than an information portal. They worked with legislators to create pathways for easier access to affordable insulin.

Chris McClure noted that it was his understanding that the legislature did not wish to create just an information portal; there would also be people available to guide and provide assistance.

Dr. Lagarde stated that she believes the question posed to the Working Group misses the mark and is presents a square peg for a round hole. She noted that the goals of the insulin bill would be met by health care coverage for the uninsured, which is being considered during the current legislative session. She mentioned that DSS has testified against the legislation.

Brad Richards noted that one key group in the uninsured population are undocumented residents.

Sue Veer re-emphasized the need for a human aspect in whatever solution the Working Group recommends, as the real goal is to ensure care is obtained. If the system manages diabetes properly, bend cost curve in right direction. Even if a diabetic patient has coverage, it is of no value unless they obtain the care.

Kara Lewis concurred that patients may also need live assistance with their coverage. Some Medicare Part D clients may need someone to review their coverage and figure out that they are eligible for a Low-Income Subsidy. This calls for a person, navigator-type role

Ms. Nally noted that our group was also established specific to the need to make insulin more accessible and affordable insulin, as the consequences are fatal if an individual does not get access to the drug.

Dr. Richards recapped, that the Working Group did not see the overall value in the referral process as described in the legislation. Instead, a care coordinator/coordination entity that could provide patient assistance with finding insulin and related diabetic care would be a more workable and helpful solution. The group may also explore whether there are other means through which the 340B program could be accessed for diabetes patients.

Vote on Referral Process

Chair Brad Richards asked for a motion to call the question posed by Public Act 20-4:

> Determine whether DSS should establish a program to assist Connecticut residents who have been diagnosed with diabetes by referring them to FQHCs and other covered entities (CEs) for treatment. (PA 20-4,Sec. 1(b)(1)(A))

Dr. Yoder moved that the vote be taken. Monica Jensen seconded the motion.

VOTE:

Yes: Fekredengle

No: Jensen, Richards, Veer, Lazarre, Nally, Yoder,

Abstain: Lagarde, McClure, Lewis, Rackliff

Vote – Alternatives to the Referral Process

Sue Veer moved that the Working Group, having voted against the referral process outlined in the statute, formally indicate its support for initiatives or alternatives that will address the needs that led to the enactment of the legislation. Sue Lagarde seconded the motion.

Motion unanimously carried.

Adjournment:

Noting that the Working Group will hold two more meetings, Dr. Richards asked for a motion to adjourn. Dr. Lagarde moved that the meeting be adjourned; Sue Veer seconded the motion. Meeting was adjourned at 10:33 am.