NJALTCPP

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VIA ELECTRONIC MAIL

Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-4182-P
P.O. Box 8013
Baltimore, Maryland 21244-8013

Re: Medicare Program; Contract Year 2019 Policy and Technical Changes Medicare Advantage, Medicare Cost Plan, Medicare Fee-For-Service, the Medicare Prescription Drug Benefit Programs and the PACE Program

Dear Sir or Madam:

On behalf of the New Jersey Association of Long Term Care Pharmacy Providers, thank you for the opportunity to comment on the Center for Medicare and Medicaid Services Proposed Policy Changes and Updates for Medicare Advantage and the Prescription Drug Benefit Program for Contract Year 2019 (CMS-4182-P). As pharmacy owners and pharmacists who have spent our professional careers in the care of seniors and people with disabilities residing in long term care facilities, we have a great deal of experience with the Medicare Part D Program and its impact on those who permanently reside in nursing homes, transition into or out of skilled nursing facilities, and reside in the community in assisted living, behavioral assisted living, congregate care and group homes. Most of the people we serve are Medicare Part D beneficiaries and over 50% are Medicaid beneficiaries. It is in this context that we respectfully submit remarks on the proposed changes to the Medicare Prescription Drug Benefit Program for the 2019 Contract Year for your review and consideration.

Limitation to the Special Enrollment Period for Dual and Low-Income Subsidy Beneficiaries.

Throughout the benefit year, Part D Plans are permitted and have historically made administrative, utilization management, price and formulary changes. We have no reason to believe that this behavior will change in 2019. Indeed, given the current health care environment, we assume that these changes will be on the increase. The problem isn't the changes per se, it's that they can have a negative impact on medication adherence for the Dual and LIS beneficiary. When Part D Plans make changes, they can affect the co-insurance rates, the amount(s) that must be contributed by the beneficiary to access the medication. A medication that did not require a co-payment, may now require one. Medication non-adherence occurs when patients cannot afford to fill their prescription(s) or decide to take less than prescribed dosage to make the prescription(s) last longer. Dual and Low-Income Subsidy beneficiaries are some of our must vulnerable

citizens; they have few options due to their income status. Medication adherence may not be an option for them in the event co-insurance requirements are increased. And when people do not maintain their medication regimens they often become sick and may require more, not less, in the way of health care services. This is precisely the reason why the initial Special Enrollment Period for Dual and Low-Income Subsidy Beneficiaries was put in place; because Part D Plans were permitted to make changes throughout the benefit year there had to be a mechanism to counter this policy and prevent medication non-adherence for our most financially insecure citizens. The facts that the proposed policy will enable Part D Plans to better administer the benefit and the current open-ended monthly Special Enrollment Period provision is not widely used, are weak arguments when compared to the harmful consequences of medication non-adherence to the individual, their family and the health care system as a whole.

When Part D Plans are no longer permitted to make changes within the benefit year, there will be no need for open-ended monthly Special Enrollment Period provision. Until that time, the New Jersey Association of Long Term Care Pharmacy Providers, opposes the proposal to limit the Special Enrollment Period for Dual and Low-Income Subsidy Beneficiaries and recommends that the current policy remain in place.

Changes in Days' Supply Requirement in Transition Period.

In long term care, patients admitted from the hospital setting and requiring skilled care will over time switch to custodial care for their remaining length of stay. Correspondingly, their initial pharmacy benefit paid for under Medicare Part A will switch to Medicare Part D, if the beneficiary does not have pharmaceutical coverage in their private insurance. For this cohort, the 90-day transition supply benefit begins the day they are admitted to the long-term care facility, whether or not they actually access the benefit. If the switch to custodial care occurs before the 90-day mark, the patient is entitled to receive transition medications for the days remaining. For example, if the switch to Medicare Part D takes place on the 29th day from admission, they can receive transition supply for up to the remaining 61(90-29) days. If the CMS proposal setting the transition fill to 30-days goes into effect, that person would be entitled to transition fill for 1 day while another person on Medicare Part A for more than 30 days will not receive a transition fill. Changes in a patient's clinical status in long term care facilities are closely assessed, monitored and (re-)evaluated in order to prevent deterioration in condition or other potential problems. Access to transition fill when a patient is moving from skilled to custodial care is important to protect patient care from disruption by providing adequate time to move over to drug that is on their Plan formulary, file an exception request or enroll in a different plan. Not all patients need to access the 90-day transition supply in order to avert a decline in their health care status, but those that do, need to. The fact that most people don't get into car accidents, does not negate the necessity for car insurance!

The proposed policy may enable Part D Plans to reduce waste, but at a potential cost to the health of the beneficiary and the health care system as a whole. In addition, the New Jersey Association of Long Term Care Pharmacy Providers recommends that in long-term care the transition fill be increased from 90 to 120 days to ensure that Medicare Part A recipients who switch to Med D after 100 days will benefit from the protections afforded by the existence of the transition fill policy.

Part D must continue to accommodate the unique requirements of people who reside in long term care facilities who are sicker and frailer than those in the community. The New Jersey Association of Long Term Care Pharmacy Providers, opposes the proposal to conform the transition supply of 90 days in the long-term care setting to the 30 days provided in the

outpatient setting and believes CMS should consider increasing transition fill to take into consideration Medicare Part A coverage parameters.

We fail to understand the value of changing the current CMS established policy and industry standard of 30/31 day transition supply to that which would give the authority to define "month" to the Plans. Depending on the month of the year and one's culture of origin, the number of days in a month will vary from 27.3 to 31. Lack of clarity and consistency in pharmacy benefits always lead to misunderstanding and confusion, resulting in coverage gaps. Whether the gap is 1 day or 5, the consequences are potentially serious. It is for this reason that we strongly urge that whenever possible, benefit parameters be concrete and not left to interpretation. From our experience, the current standard of 30/31 is widely known and works well, so, why "fix" it? Unless we are mistaken, the only value of changing this requirement from actual number of days to the less concrete "one month" is for the Plans to save money on the proverbial backs of the beneficiaries.

The New Jersey Association of Long Term Care Pharmacy Providers opposes the proposed change to transition supply requirement from the current, "thirty-day" to "a one month" supply because it de-concretizes and de-clarifies the policy in such a way that would be a disadvantage to Part D beneficiaries.

Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes

Though we agree with the effort to keep costs down, we do not believe that the CMS proposal to permit Part D sponsors to immediately substitute newly released therapeutically equivalent generics for brand name drugs can be operationalized in the long-term care setting. First, without proper notification the long-term care pharmacy which dispenses 24/7, at night or on a weekend may not have in-stock the newly released therapeutically equivalent generic drug, and will have to wait to order during regular business hours from their wholesale distributor. Second, though for new admissions the long-term care pharmacy often does not have relevant billing information, it is required by government regulations to provide a quick turnaround and timely delivery of prescriptions. Under this common scenario, pharmacy will not be aware of a formulary change until the adjudication process, after the medication has been dispensed. It is for these reasons that we believe that Part D Plans must bear some responsibility to immediately inform their network long term care pharmacies of the substitution and require compliance in a realistic time-frame. Otherwise and through no fault of their own, the cost savings will be borne on the shoulders of the pharmacy.

Because of the existence of round-the-clock dispensing and post-consumption billing in the long-term care pharmacy, the New Jersey Association of Long Term Care Pharmacy Providers recommends that the Plans be required to notify network long-term care pharmacies of generic substitutions in a pre-established, specific number of days prior to procedural effectuation.

In long term care, receipt of official notification is not always immediate when the resident is under the care of a guardian. In cases where the guardian visits on a monthly or quarterly basis and because facilities are not permitted to open a resident's mail, a prompt decision regarding the (re)arrangement of appropriate and quality care may not always be achievable. The proposal to reduce notice and refill requirement from 60 to 30 days in instances where removal of a drug or change in the cost share status will affect enrollees currently taking the drug won't be fair to the beneficiary under guardianship in a long-term care setting. In instances when communications are not picked up on a constant basis by the guardian, a 60-day span will at least enable the facilities to forward mail notification to the guardian to (hopefully) give them enough time to

move the ward over to another drug or enroll in a new Part D Plan. 30 days will cut this time frame too close and negatively impact the beneficiary.

Given the realities of communication in long term care facilities, the New Jersey Association of Long Term Care Pharmacy Providers opposes the proposal to reduce notice and refill requirement from 60 to 30 days in certain instances and recommends that the current 60-day requirement remain in place.

Preclusion List Requirements for Prescribers in Part D

CMS proposes eliminating the prescriber enrollment requirement and compiling a "Preclusion List" which it would make available to the Plan which would be required to deny claims from or written by prescribers on the list. For new admissions, long-term care pharmacies often dispense the medication(s) without entering a claim in real-time because the relevant information received from the long-term care facility on the patient is incomplete. If this occurs with a provider on the "Preclusion List," a long-term care pharmacy would either have to spend resources to fight denial of payment or bear the cost. Including the long-term care pharmacy on the distribution list, would ensure that this important CMS policy is upheld without undo cost to the pharmacy and health care system.

Given the realities of the admissions process in long term care, the New Jersey Association of Long Term Care Pharmacy Providers requests that there be a standard process by which the Plans or CMS inform the long-term care pharmacies of providers included on the "Preclusion List" in order to prevent the long-term care pharmacies from inadvertently filling these prescriptions.

Manufacturer Rebates and Pharmacy Prices Concession to Point of Sale.

CMS proposes Return on Investment to require sponsors to include a percentage of their manufacturer's rebates and all pharmacy cost concessions received. The New Jersey Association of Long Term Care Pharmacy Providers is in full support of increased transparency. Please note that any rebates and cost concessions that have been realized by the insurers have, regrettably, not been realized by the pharmacies.

Thank you for your review and consideration of our recommendations.

Sincerely,

Robert Fusco

Robert Fusco