**VIA Electronic Submission at:** <http://www.regulations.gov>

January 16, 2018

Seema Verma

Administrator of the Centers for Medicare and Medicaid Services

Department of Health and Human Services

Attention: CMS-4182-P

P.O. Box 8013

Baltimore, MD 21244-8013.

**Re:** **Proposed Rule for Contract Year 2019, Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (CMS-4182-P).**

Dear Administrator Verma,

Genoa, a QoL Healthcare Company appreciates the ability to comment on the above referenced rules.

Genoa builds on-site full-service pharmacies for the Mental Health Community. We understand the unique and special needs of the severe and persistent mentally ill (SPMI) population. Our 394 pharmacies in 45 states and DC offer full service, confidential and discrete pharmacy services to clients, and present a convenience for filling prescriptions. Our pharmacies have very low rates of unclaimed prescriptions, resulting in higher compliance and lower overall healthcare costs. We also specialize in helping patients apply for Patient Assistance Programs, stay adherent to their medication regimen, manage the dispensing and inventory of samples, and helping complete prior authorizations. Recent studies have shown that Genoa’s 96% adherence rate results in a 40 percent reduction in behavioral health related hospitalizations and 18% reduction in behavioral health related emergency room visits. This patient centered model saves the healthcare system $700 per patient per year. Genoa served 550,000 patients in 2017 resulting in an overall savings of $385M.

***Pharmacy Lock in Program***

Genoa supports the CMS proposal *“that where a pharmacy has multiple locations that share real-time electronic data, all locations of the pharmacy collectively be treated as one pharmacy under the clinical guidelines.”* Genoa understands and supports the goal of a lock-in program to help reduce pharmacy shopping and drug diversion. However, all of our pharmacies share data and we believe that treating each pharmacy owned and operated under the same entity as an individual pharmacy is unnecessary. The ability to use a Genoa pharmacy in a different location increases patient access to our services. Genoa supports a beneficiary’s ability to provide pharmacy preferences to which pharmacy they would be “locked in”. People living with a mental illness are do not like change, they need structure. This will allow them to continue to use the pharmacy at which they feel comfortable and receive the best service.

***Manufacturers Rebates and Direct and Indirect Remuneration Fees***

Genoa supports CMS’s efforts, through this proposal, to improve drug price transparency for Medicare beneficiaries. Over 45% of Genoa’s patients receive Medicare benefits. As drug prices rise, it is these patients that are most impacted. Unfortunately, our patients face the full brunt of high drug prices as such beneficiaries do not currently benefit directly from manufacturer rebates used to lower the price. This problem is especially troublesome for beneficiaries taking Long Acting Injectable Medications as they can face a financially debilitating copayment. The situation is exacerbated as our patients typically take four times the number of monthly medications when compared to people without a behavioral health condition. This financial impact results in members abandoning their drug therapy, leading to negative health outcomes and ultimately higher overall medical costs.

While modifications to benefit design and risk mitigation strategies should be reviewed by CMS to align with the goals of not increasing government costs or reducing manufacturers payments under the coverage gap discount program, Genoa believes point-of-sale rebates will lower out of pocket costs for beneficiaries and make medicine more accessible.

Genoa opposes the Pharmacy benefit manager’s ability to arbitrarily dictate the final price of a medication. Healthcare is the only entity where a business is paying for a product without knowing it’s final price. Many times Genoa has purchased a medication, dispensed it, adjudicated the claim, only to have the PBM assesses DIR fees at a later time. Genoa requests that CMS take steps to prohibit this process by updating the requirements governing the determination of negotiated prices to better reflect current pharmacy payment arrangements. This will help ensure that the reported price at the point-of-sale includes all pharmacy price concession

***Pharmacy Accreditation***

In the rules, the CMS states that it does not expect Part D plan sponsors to limit dispensing of certain drugs or drugs for certain disease states to a subset of network pharmacies, except when necessary to meet FDA-mandated limited dispensing requirements or except as required by applicable state law or laws. Genoa strongly supports this policy. Genoa requests that the CMS strengthens this policy from an expectation to a prohibited act. It is critical for those living with mental illness to have access to their medication. For our patients, a one day gap in therapy greatly increases the risk of hospitalization, or a visit to the emergency room. People living with mental illness do not accept change well. In many cases, if they have to change pharmacies or are required to receive their medication via mail order, they simply will stop taking that medication.

***Pharmacy Networks***

Genoa supports that the CMS is clarifying that Part D plan sponsors may not exclude pharmacies with unique or innovative business or care delivery models from participating in their contracted pharmacy network based on not fitting in the correct pharmacy type classification. Genoa believes we are an innovative business model and this will prohibit plan sponsors from excluding us.

Genoa also strongly agrees with CMS that Part D plan sponsors should not limit dispensing of certain drugs or drugs for certain disease states to a subset of network pharmacies, except when necessary to meet FDA-mandated limited dispensing requirements (for example, REMS processes) or except as required by applicable state law(s) if the contracted network pharmacy is capable of and appropriately licensed under applicable state law(s) for doing so.

As previously mentioned, changes in routine can be especially challenging for mental health patients. Narrowing the network to exclude our pharmacies causes our patients great consternation and can cause them to stop taking their medication, resulting in possible decompensation events. Genoa has experienced problems within this area within Medicaid where plans have required long acting injectable medications to be dispensed by mail order pharmacies. In one case, a patient who received their injectable in the mail broke the glass tube and tried to drink the liquid. This clarification will help keep this from happening in Part D.

***Timing of Contracting Requirements***

In the proposed rule, CMS states it has received complaints over the years from pharmacies that have sought to participate in a Part D plan sponsor’s contracted network but have been told by the Part D plan sponsor that its standard terms are not available until the sponsor has completed all other network contracting. Genoa supports improving the timing of contract requirements.

However, a greater challenge has arisen regarding when a Part D plans changes it’s plan design. Genoa requests that CMS require Part D plans to provide advance notice prior to any design change. In the past, these changes have taken place without much, if any notice. These changes cause confusion and concern within our patient population. By providing at least a 30 day notice, it would allow our pharmacists to explain a design change to their patients, thus preparing them for the change.

***NCPDP SCRIPT***

While Genoa supports the proposal to adopt NCPDP SCRIPT Standard Version 2017071, we feel it will be difficult to meet the January 1, 2019 effective date. It will take Genoa longer to plan for these changes, and implement the new Standard. Genoa would also request that a transition period be added to the timeline. The implementation should include a voluntary use date to be the effective date of the Final Rule and the sunset date for SCRIPT Version 10.6 be 36 months later. This correlates with the amount of time needed when changing from SCRIPT Version 8.1 to Version 10.6 and will help decrease the risk of healthcare delivery delays. Furthermore, Genoa requests that the compliance date occur later in the year so as to not coincide with the January 1 plan changes.

***Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes***

Genoa supports the CMS proposal to permit Part D sponsors to immediately remove, or change the preferred or tiered cost sharing of, brand name drugs and substitute or add therapeutically equivalent generic drugs. By decreasing this timeframe, it increases access to lower cost medications for beneficiaries, and decreases costs to pharmacies through decreased inventory carrying costs for brand name drugs.

Respectfully,

John Figueroa

Chief Executive Officer

Genoa