ORDER GRANTING MOTION FOR SUMMARY JUDGMENT

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I. **FILINGS**

This Order is being issued in response to the following:

(a) Community Insurance Company’s (“CIC”) Hearing Request dated June 4, 2021;
(b) Community Insurance Company’s Motion for Summary Judgment and Prehearing Brief (“CIC’s MSJ”) dated June 11, 2021;
(c) Centers for Medicare & Medicaid Services’ (“CMS”) Brief in Reply to Applicant’s Brief (“CMS’ Brief”) dated June 18, 2021; and

II. **ISSUE**

Whether CIC has proven by a preponderance of the evidence that CMS’ denial to offer new Part D services, based upon an alleged failure to meet contracting application requirements, was inconsistent with regulatory requirements.

III. **SUMMARY OF DECISION**

The Hearing Officer grants CIC’s Motion for Summary Judgment. Neither the parties nor the Hearing Officer have identified any disputed material facts. As background, the evaluation regarding whether the contractual payment provisions submitted were detailed enough to meet federal requirements is, to a degree, subjective. Moreover, within the parameters of 42 C.F.R. part 423, subpart K (Application Procedures and Contracts with Part D plan sponsors), CMS firmly maintains the right to have applicants provide information or revise their application in the form and manner that the CMS reviewer expects, even if an applicant subjectively believes that their submission is otherwise adequately descriptive. 42 C.F.R. §§ 423.502(c) and 423.503(c). At the same time, within CMS’ application process, it is also required to give an applicant a fair opportunity to cure any identified deficiencies. 42 C.F.R. § 423.503(c).

In this case, CMS’ deficiency notices to CIC were unintentionally ambiguous and misleading, as they imprecisely indicated that the materials under review did not contain finalized payment or consideration terms. In fact, the materials did contain payment terms, although not to the specificity that CMS expected and believed was required. Additionally, CIC reasonably understood CMS’ subsequent communications as merely requesting an unexecuted clarification relating to existing payment terms, as opposed to also requesting a new, formally executed contract or modification. As such, the Hearing Officer finds that, given the totality of the circumstances, CIC was deprived of a full and fair opportunity to cure its alleged deficiencies in accordance with CMS’ application and review process and 42 C.F.R. § 423.503. The Hearing Officer finds that CIC has proven by a preponderance of the evidence that the level of specificity within the originally submitted contracts could satisfy the minimum substantive requirements of 42 C.F.R. § 423.505, and thus the application is approvable.
IV. APPLICATION AND REVIEW PROCESS (GENERALLY)

The Social Security Act ("the Act") authorizes CMS to enter into contracts with entities seeking to offer Medicare Advantage ("MA"), or Part C, benefits, and Medicare outpatient prescription drug ("Part D") benefits to their plan enrollees. Social Security Act §§ 1857 and 1860D-12. An organization may not offer MA or Part D benefits unless it has entered into a contract with CMS. Id. at §§ 1857(a) and 1860D-12(b)(1). CMS has the regulatory authority to set the form and manner for the submission of applications for qualification as a Part D plan sponsor. See 42 C.F.R. §§ 423.502(c) and 423.504(b)(1). Pursuant to § 423.502(c)(1), organizations intending to offer Part D benefits must complete a certified application in the “form and manner” required by CMS.\(^1\) Applicants must also “describe thoroughly how the entity is qualified to meet” the regulatory requirements. 42 C.F.R. § 423.502(c)(2). Applications are submitted to CMS through the Health Plan Management System ("HPMS").

CMS conducts a review of all submitted Part D applications pursuant to § 423.503 and issues determinations consistent with § 423.503(c). When evaluating applications, “CMS evaluates an application for a MA contract . . . solely on the basis of information contained in the application itself and any additional information that CMS obtains through other means such as on site visits.” 42 C.F.R. § 423.503(a)(1). CMS reviews the application to determine whether it meets all of the necessary requirements. 42 C.F.R. § 423.503(a)(2). CMS then notifies the applicant of any deficiencies by emailing a courtesy notice of deficiencies and specifying a date by which the deficiencies are to be cured. This is an applicant’s first opportunity to amend its application.

If an applicant fails to remedy all of the deficiencies in its application by the specified date, or if CMS determines that the plan is not able to meet the requirements to become a Part D sponsor in the requested service area, then CMS issues a Notice of Intent to Deny (“NOID”). 42 C.F.R. § 423.503(c)(2)(i). The NOID contains a summary of the basis for CMS’ preliminary finding. An applicant that receives a NOID is provided ten days from the date of notice to respond, in writing, to CMS’ preliminary findings and to revise its application remedying any defects that CMS has identified. 42 C.F.R. § 423.503(c)(2)(ii). The formal NOID process is outlined at 42 C.F.R. § 423.503(c)(2)(i)–(iii), which states:

1. If CMS finds that the applicant does not appear to contract as a Part D sponsor, it gives the applicant notice of intent to deny the application and a summary of the basis for this preliminary finding.

2. Within 10 days from the intent to deny, the applicant must respond in writing to the issues or other matters that were the basis for CMS’ preliminary finding and must revise its application to remedy any defects CMS identified.

\(^1\) 42 C.F.R. §§ 423.500-520 specifically governs the Application Procedures and Contracts with Part D plan sponsors. 42 C.F.R. § 423.500 specifies, however, that “[f]or purposes of this subpart, Medicare Advantage (MA) [Part C] organizations offering Part D plans follow the requirements of part 422 of this chapter for MA organizations, except in cases where the requirements for the qualified prescription drug coverage involve additional requirements.”
(iii) If CMS does not receive a revised application within 10 days from the date of the notice, or if after timely submission of a revised application, CMS still finds that the applicant does not appear qualified or has not provided CMS enough information to allow CMS to evaluate the application, CMS will deny the application.

In the final rule regarding the MA prescription drug applications procedure and how it will assist plans in their understanding of deficiency notices, CMS stated:

All application communications include contact information for CMS subject matter specialists. We are always willing to work with applicants to ensure a complete understanding of program and contracting requirements. 75 Fed. Reg. 19678, 19683 (Apr. 15, 2010).

To this end, in its courtesy notice of deficiencies and NOID, CMS provides a specific point of contact for the listed deficiencies. CIC Exhibits P-4 and P-7.

If an applicant fails to submit a revised application within ten days from the date of the NOID issuance, or CMS believes that a revised application fails to meet the necessary requirements to contract as a Part D plan sponsor in the requested service area, CMS denies the application. 42 C.F.R. § 423.503(c)(2)(ii)–(iii). If, after review, CMS denies the application, written notice of the determination and the basis for the determination is given to the applicant. 42 C.F.R. § 423.503(c)(3).

If CMS denies a Part D application, the applicant is entitled to a hearing before a CMS Hearing Officer and may request a hearing within fifteen calendar days after the receipt of the denial. 42 C.F.R. § 423.503(c)(3)(iii). The applicant has the burden of proving by a preponderance of the evidence that CMS’ determination was inconsistent with the requirements of 42 C.F.R. §§ 423.502 (application requirements) and 423.503 (evaluation and determination procedures). 42 C.F.R. § 423.650(b)(1). In addition, either party may ask the Hearing Officer to rule on a Motion for Summary Judgment. 42 C.F.R. § 423.662(b). The authority of the Hearing Officer is found at 42 C.F.R. § 423.664, which specifies that “[i]n exercising his or her authority, the hearing officer must comply with the provisions of title XVIII [of the Social Security Act] and related provisions of the Act, the regulations issued by the Secretary, and general instructions issued by CMS in implementing the Act.”

V. AUTHORITY RELATING TO CONTRACT EXECUTION AND PAYMENT TERMS

The Part D regulations at 42 C.F.R. § 423.505(i)(1) provide that plan sponsors may contract with other entities to perform Part D related functions on the sponsor’s behalf. The regulation also mandates that contracts contain mandatory terms as well as terms “CMS may find necessary and appropriate in order to implement requirements in this part.” 42 C.F.R. § 423.505(i)(3) and (j).
The final Solicitation was posted on CMS’ website on December 30, 2020. The Solicitation required entities seeking to contract as a Part D plan sponsor to submit applications through the HPMS. The HPMS-generated application requires that the applicant prove, through attestations and supporting documentation, that it meets certain requirements. With regard to an applicant delegating the performance of certain Part D functions to “first tier, downstream, or related entities,” the applicant must identify the entities, their relationship, the function(s) to be delegated, and submit a copy of an executed contract memorializing these items. See Solicitation at § 3.1.1.C-E, CMS Exhibit C-1 at 003-007. Additionally, the Solicitation at § 3.1.1.E. addresses the requirement that executed contracts (very generally) describe payment/consideration terms. The Solicitation states:

E. [U]pload copies of executed contracts, fully executed letters of agreement, administrative services agreements, or intercompany agreements . . . with each first tier, downstream or related entity identified in Sections 3.1.1.C . . . and with any first tier, downstream, or related entity that contracts with any of the identified entities on the applicant’s behalf . . . . Unless otherwise indicated, each and every contract must:

5. Describe the payment or other consideration the parties have agreed that the first tier, downstream, or related entity will receive for performance under the contract . . . .

7. Be signed by a representative of each party with legal authority to bind the entity.

See Solicitation at § 3.1.1.E., CMS Exhibit C-1 at 005-006.

VI. PROCEDURAL HISTORY AND STATEMENT OF FACTS

In 2004, a Master Administrative Services Agreement (“MASA”) was executed by WellPoint Health Networks Inc., which later changed its name to Anthem, Inc. (“Anthem”). See CMS’ Response Brief at 3, n.1. The MASA was designed to facilitate shared administrative and support services between Anthem’s subsidiaries. CIC Exhibit P-1 at P002-024. CIC is a subsidiary of Anthem and a party to the MASA. Declaration of Denise King, ¶ 3 (“King Decl.”). Relevant to these proceedings, the MASA contains the following provisions:

2 https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ApplicationGuidance.
SECTION 2. RESPONSIBILITIES OF THE COMPANIES.

2.1 Provision of Services. Subject to the requirements, limitations or prohibitions of any applicable statute or regulations, the Companies shall provide such administrative, consulting and other services to each other as are set forth in the Attachments hereto and as may be executed from time to time. Any and all Attachments shall be subject to all of the terms and conditions set forth in this Agreement and to any additional terms and conditions as shall be set forth in such Attachment. Each Attachment shall be deemed to be a part of this Agreement with respect to the Companies that are parties to such Attachment.

....

SECTION 3. COMPENSATION.

3.1 Amount of Compensation. Subject to any restrictions of applicable law, each Company receiving any of the foregoing services from another Company shall pay the Company providing the services reasonable compensation, in accordance with the provisions of the applicable Attachment.

3.2 Payment Date; Substantiation of Costs and Expenses.

   (a) A Supplying Company shall bill each Receiving Company receiving such services in accordance with the provisions of the applicable Attachment. Any Receiving Company shall promptly pay such compensation to the Supplying Company, subject to reasonable review and verification of the amounts billed. The Supplying Company providing the services shall provide any information reasonably required by the Receiving Company for this purpose.

   (b) WellPoint and the Companies shall, where appropriate, directly trace costs for services directly to the end-user of such services. For such services where it is not appropriate to trace costs directly to an end-user, WellPoint and the Companies shall utilize allocation methodologies (i.e., proxies such as headcount, premium and premium equivalents, membership, and so forth) in conformity with generally accepted accounting principles and statutory accounting guidelines, Internal Revenue Service guidelines and customary insurance accounting principles, all consistently applied. Subject to any other agreements between the parties hereto, all costs and expenses shall be allocated in a fair and reasonable manner. The parties shall establish reasonable and
appropriate operating procedures with respect to the allocation of costs and expenses so as to enable the parties' independent certified public accounting firm to audit such costs and the allocation thereof. With each billing, the Supplying Company shall provide to the Receiving Company appropriate documentation respecting the costs and expenses which are the subject of the billing in sufficient detail to permit the Receiving Company to identify the sources of such charges.

SECTION 9. GENERAL PROVISIONS.

9.7 Amendment. This Agreement shall be effectuated and supplemented by Various Attachments, as set forth in SECTION 2 hereof, as some or all of the parties hereto may, from time to time, enter into. This Agreement and the Attachments hereto may be amended at any time by a writing executed by the parties hereto.

CIC Exhibit P-1 at P003, P006-007, P011.

Pursuant to the terms of the MASA, a Memorandum of Understanding ("MOU") was executed in order for IngenioRx, Inc. ("IngenioRx"), another subsidiary of Anthem, to provide pharmacy benefit services to Anthem’s subsidiaries, including CIC. Id. at P025-032. IngenioRx was approved by CMS to provide the same services to other Part D plan sponsors pursuant to the same MASA and MOU. King Decl. at ¶ 4; CIC Exhibits P-13 and P-14. The MOU contains the following provision:

2. Compensation for Services Rendered. Subject to any restrictions of applicable law, each Health Plan receiving any of the foregoing Services from the PBM shall pay the PBM reasonable compensation in accordance with the MASA.

   a. The state and line of business specific schedules that are part of the agreement between CVS and PBM detail the specific Services provided by CVS and the pricing for those Services. The pricing set forth in those schedules shall be billed to the appropriate Health Plan at cost and without markup.

   b. Services provided by the PBM that are not listed on the schedules identified in 2.a. shall be reimbursed through cost based allocation in accordance with the MASA.

Exhibit P-1 at P030.
On February 17, 2021, CIC submitted its Part D application to CMS, which included the MASA and MOU. CMS Response Brief at 3. On March 23, 2021, CMS issued a courtesy notice of deficiencies, which included the following deficiency:

- The contract your organization submitted for key Part D functions does not contain finalized payment or consideration terms. The contract referenced is between WellPoint Health Networks and Community Insurance Company. CIC Exhibit P-4 at P748.

CIC submitted curing materials on March 31, 2021, none of which attempted to address this deficiency. The curing materials included a new, fully executed, amendment to the MOU with IngenioRx (“Amendment 50”). Amendment 50 was submitted to cure other deficiencies cited by CMS in its courtesy notice of deficiencies, but did not address or clarify any payment terms. CMS’ Response Brief at 3; CIC MSJ at 1. On April 19, 2021, CMS issued a NOID, which included the following deficiency:

- The contract your organization submitted for key Part D functions does not contain finalized payment or consideration terms. The contract referenced is between WellPoint Health Networks and Community Insurance Company. Please contact CMS at PartD_Applications@cms.hhs.gov to clarify certain pricing terms. CIC Exhibit P-7 at P810.

On April 20, 2021, Anthem’s Compliance Policy & Strategy Director, Denise King, contacted CMS about the deficiencies identified in the NOID. CIC Exhibit P-8 at P813-15. The next day, CMS replied that it “would like to discuss and better understand your contract pricing terms.” Id. at P813. On April 22, CIC and CMS representatives had a call to discuss the payment terms, and CMS indicated it needed additional detail on how costs would be allocated. CMS Response at 4; CIC MSJ at 4; King Decl. at ¶¶ 11-12. CIC insists that CMS never expressly mentioned or requested an updated contract or signature page when discussing what types of clarification it would require, and CMS does not dispute this fact anywhere in its brief. CIC MSJ at 5; King Decl. at ¶ 14. CMS specifies it told CIC that the contract would need to describe a price or an identifiable methodology for cost-based reimbursement. CMS Response at 4.

On April 29, 2021, CIC uploaded curing materials to HPMS, including the addition of clarifying language to Amendment 50, for the payment terms relating to how costs would be allocated on a member per month basis. CIC represents that it “was further clarifying the payment terms per CMS’s request.” King Decl. at ¶ 20; CIC Exhibit P-9 at P863. The new language read:

20. For the purpose of determining cost-based compensation for services rendered by [the pharmacy benefit manager (“PBM”)] to Health Plans under Paragraph 2.b of the MOU for Medicare enrollment, costs will be allocated on a per member per month basis. To determine the allocation for any Medicare Benefit Period, the parties will first determine the expected costs to be incurred by PBM for services payable under Paragraph 2.b of the MOU during that
Medicare Benefit Period for all Health Plan enrollment (Medicare and non-Medicare). The result will be divided by the annualized number of Medicare and non-Medicare members in all Health Plans that is projected to be enrolled during the Medicare Benefit Period. The resulting amount will be the per Member per month amount charged to a Health Plan for its Medicare enrollment. This calculation will be made no later than 90 days prior to the beginning of that Medicare Benefit Period. CIC Exhibit P-9 at P863.3

CMS notes that nothing in the clarifying language above indicated that this was an agreed upon change to the contract. CMS Brief at 4.4 Accordingly, on May 27, 2021, CMS denied CIC’s application under contract H7093 based on the payment terms, specifically stating:

The contract your organization submitted for key Part D functions does not contain finalized payment or consideration terms. The contract referenced is between WellPoint Health Networks and Community Insurance Company. CIC Exhibit P-11 at P873.

CIC filed a Request for Hearing on June 4, 2021. A Notice of Hearing was issued the same day, setting forth briefing deadlines and a hearing date. CIC has moved for summary judgment, and while CMS opposed CIC’s request, it concurred that this matter could be resolved on the written record without a hearing.

VII. DISCUSSION, FINDINGS OF FACT AND CONCLUSIONS OF LAW

CIC raises three arguments in its appeal. First, it claims that the payment term requirements underlying CMS’ denial are found in the Part D application instructions, but not in a properly promulgated regulation, and are thus not enforceable standards for eligibility. CIC’s MSJ at 6-9 (citing Azar v. Allina Health Servs., 139 S.Ct. 1804 (2019) (“Allina”)). Second, CIC argues that even if the payment term requirements are enforceable, the contracts submitted with the initial application on February 17, 2021 (and which were resubmitted, unchanged, on March 31, 2021 following the courtesy notice of deficiencies) satisfied the requirements. CIC’s MSJ at 9-12; CIC’s Reply Brief at 3-5. Finally, CIC states that the clarifying language submitted on April 29, 2021 following the NOID did, in fact, cure the deficiency in the manner that CMS directed and was also

3 With regard to the legal significance of the clarifying language in relation to the original agreement, CIC asserts that the language “did not alter the intent or operation of the existing agreement between Anthem subsidiaries and IngenioRx.” King Decl. at ¶ 17; Declaration of Kristin Stenger (“Stenger Decl.”) at ¶ 5; see also CIC Exhibit P-9 at P863. Instead, it simply reflected the existing course of conduct that was already in place, which was well known and agreed to by the parties. King Decl. at ¶ 17; Stenger Decl. at ¶¶ 4-5. CIC and IngenioRx were each aware that CMS had requested the additional clarifying language and each agreed that the additional language reflected the parties’ original and already existing agreement. King Decl. at ¶¶ 17-19; Stenger Decl. at ¶¶ 2, 6.

4 CIC represents that when it submitted the clarifying language to CMS, it did not believe it was necessary to provide new signatures. CIC explains, “Because CMS never requested any change to a signature page, CIC did not believe any change to be necessary because the additional language reflected existing practice; the respective parties are related; each party approved the language and its submission to CMS; and the underlying agreement was already signed and binding.” King Decl. at ¶¶ 15-19; see also Ex. P-9 at P 825, P 828, P 846-847, P 864.” CIC’ MSJ at 5.
a binding contract despite the fact that it did not have a new signature page. CIC’s MSJ at 12-15; CIC’s Reply Brief at 6-8; King Decl. at ¶¶ 16-19; Stenger Decl. at ¶¶ 2-5.

CMS counters that nothing was included in the application materials to indicate that the clarifying payment terms, CIC Exhibit P-9 at P863, were an “agreed upon change” to the contract. CMS Brief at 4. CMS emphasizes that it makes a contract qualification determination concerning a Part D application solely on the basis of the information in the application itself.5 Moreover, the requirements underlying its denial are not just found in the Part D application instructions, but are actually found in regulations which require a “contract,” which by its usual definition requires signatures. CMS explains that “[i]nherent in the use of the term contract at 423.505(i) and other locations within the Part D regulations is the requirement that the definition of a contract is met in each document provided; that is, offer, acceptance, and consideration are required to form a binding agreement.” CMS Response at 4-5. As such, it rejects CIC’s argument that the signature requirement is invalid under the holding in Allina. CMS argues that the language in the original contracts submitted on February 17, 2021 and March 31, 2021 were insufficient because “reasonable compensation” is not defined. Furthermore, even though identical language within these same contracts was accepted by CMS in the past, it notes that the application instructions caution applicants not to rely on their experience from prior years, and that an error made by CMS in the past does not obligate it to repeat or accept the same error in perpetuity. Id. at 6.

The regulation at 42 C.F.R. § 423.664 dictates that the Hearing Officer must comply with the provisions of Title XVIII of the Act (Health Insurance for the Aged and Disabled), related provisions of the Act, regulations issued by the Secretary of Health and Human Services, and general instructions issued by CMS in implementing the Act.

The Hearing Officer notes that a reviewer’s evaluation of whether the payment terms at issue are detailed enough to meet CMS’ standards is, to a degree, subjective. The Part D applicant is required to submit an executed contract that “describe[s] the payment or other consideration the parties have agreed [will be received] for performance under the contract.” Solicitation at § 3.1.1.E.5, CMS Exhibit C-1 at 006. The agreement specified that payment will, when possible, be subjected to cost-based allocation. That is, the amount of payment will be whatever can be traced directly to specific costs or services being reimbursed. If such direct tracing is not possible, the materials also specified that the parties agree to use generally accepted methods (with examples provided) to determine a reasonable payment for that specific cost. On the other hand, from a substantive standpoint, CMS expected an additional layer of detail, which CIC eventually presented (albeit, unexecuted) on April 29, 2021. The Hearing Officer finds that CIC has proven by a preponderance of the evidence that the level of specificity within the original MASA and MOU satisfied the minimum substantive requirements of 42 C.F.R. § 423.505 and the Solicitation.

Within the parameters of 42 C.F.R. part 423, subpart K (which governs the application and review process), and specifically 42 C.F.R. §§ 423.502(c) and 423.503, CMS maintains the right to require applicants to provide information or revise their application in the form and manner that CMS expects, even if an applicant subjectively believes that the materials submitted are adequately

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5 In certain instances which are not applicable here, CMS may collect information through a site visit or an essential operation test. 42 C.F.R. § 423.503(a)(1). See also CMS Brief at 5.
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descriptive. At the same time, CMS is required to give an applicant a fair opportunity to cure any identified deficiencies. 42 C.F.R. § 423.503(c)(2).

In this case, from the onset, the initial communication within the courtesy notice of deficiencies and NOID statements that the contracts did “not contain finalized payment or consideration terms” were ambiguous and misleading. As noted above, the contracts were finalized and contained reasonably specific payment terms, even if they did not meet CMS’ expectations. Neither the courtesy notice of deficiencies or NOID specified that the contract terms were inadequate or needed additional detail, but rather, implied that they did not exist.

Further, the NOID specifically noted a point of contact for CIC to “clarify certain pricing terms.” CIC Exhibit P-7 at P810. When CIC reached out, they were informed that CMS “would like to discuss and better understand your contract pricing terms.” CIC Exhibit P-8 at P813. CIC claims, and nothing in the record or in either party’s briefs suggest otherwise, that CMS never expressly requested a formal, newly executed amendment to any of the contracts. Following a discussion between the parties, CIC submitted additional clarification as requested by CMS that, from a substantive perspective, expanded on the calculation methodology already found in the MASA and MOU.

The Hearing Officer finds that CIC has met its burden in proving, by a preponderance of the evidence, that CMS’ denial of its application was inconsistent with a fair interpretation of the controlling authority. CMS’ courtesy notice of deficiencies and NOID imprecisely claimed that the contracts at issue did not have finalized payment or consideration terms, when in reality the deficiency was that while the terms existed, CMS viewed them as inadequate. When CIC and CMS eventually discussed the original miscommunication relating to CMS’ substantive expectations, CMS requested “clarification” rather than a newly signed contract or amendment. The Hearing Officer finds that CMS’ communications were to a degree, ambiguous and misleading, and CIC was unintentionally deprived of a full and fair opportunity to cure them in accordance with 42 C.F.R. §§ 423.502(c) and 423.503.

Given the finding that the original submissions satisfied CMS’ application requirements, the Hearing Officer will not reach CIC’s arguments regarding whether the Part D application requirement for an executed contract violates Allina or whether the additional language in the April 29, 2021 submission (Amendment 50) constitutes a valid contract without a fresh signature.6

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6 CIC cites state case law for the premise that parties may amend agreements without a signature, which is not legally required to make a contract binding. CIC’s Reply Brief at 7.
VIII. ORDER

CIC’s Motion for Summary Judgment is granted.

Benjamin Cohen
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Benjamin R. Cohen, Esq.
CMS Hearing Officer

Date: August 11, 2021