

#### **MEMORANDUM**

DATE: May 22, 2017

TO: VaxCare, Inc.

FROM: Thomas N. Bulleit

Lisa Q. Guo

SUBJECT: Memorandum on Mass Immunizer, Rural Health Clinic, and Federally Qualified

Health Center Medicare Billing

#### I. INTRODUCTION AND EXECUTIVE SUMMARY

VaxCare is enrolled as a "mass immunizer" provider under Medicare. VaxCare contracts with physicians, including Rural Health Clinic ("RHC") and Federally Qualified Health Center ("FQHC") physicians, for the administration of influenza and pneumococcal vaccines. VaxCare is the Medicare provider of these vaccines and bills Medicare for both the vaccine and administration (the "VaxCare Model"). You asked us to look into whether VaxCare's billing of Medicare for vaccines and their administration as a mass immunizer might be duplicative of a Medicare billing by a RHC or FQHC and whether there are any other prohibitions under RHC or FQHC billing rules on RHC or FQHC physicians contracting with VaxCare as described.

In summary, we believe it is reasonable to conclude that VaxCare's contracts with RHCs and FQHCs, if implemented in the manner described, would not be duplicative of RHC or FQHC billing so long as RHCs and FQHCs, when reporting general allowable costs to Medicare, carve out staff time and other overhead costs related to administering vaccines on behalf of VaxCare (in essentially the same manner that RHCs and FQHCs already are instructed to do to obtain Medicare reimbursement when the RHC or FQHC is billing for vaccine). We also believe it is reasonable to conclude that Medicare guidance does not prohibit RHCs and FQHCs from contracting with VaxCare to perform administration of vaccines for VaxCare under the VaxCare Model.

#### II. FACTUAL BACKGROUND

VaxCare is a health care information and technology company that provides an inventory management and dispensing solution for vaccines. VaxCare's service offering allows vaccination of the Centers for Disease Control and Prevention ("CDC")-recommended schedule of all ages across multiple immunizing specialties: pediatrics, family practice, internal medicine, and public health departments. Enrolled in Medicare as a "mass immunizer," and under contract to private health care

payers as a provider, VaxCare's business model focuses on serving the patients of physicians with whom VaxCare contracts for administration of vaccine supplied by VaxCare. The VaxCare platform is integrated with the systems of the five major vaccine manufacturers (Sanofi Pasteur; Merck & Co., Inc.; GlaxoSmithKline plc; Pfizer Inc.; and AstraZeneca plc) and into state immunization registries in states where its service is offered.

Here is how the VaxCare Model works.

# VaxBuy

When a physician office contracts with VaxCare, the company provides vaccines on a consignment basis to the physician office. With VaxCare, the physician does not place vaccine orders with a manufacturer or distributor. Instead, VaxCare uses predictive algorithms to forecast the physician office's vaccine usage and establish minimum participation threshold inventory levels. VaxCare aims to provide 3-6 weeks of vaccine inventory at the participating physician's office.

VaxCare has direct contracts with vaccine manufacturers to purchase vaccines and uses different distributors to handle the shipping and delivery of the vaccines. All vaccine orders are drop shipped directly to the physician office. Through its proprietary logistics platform, VaxCare's inventory is tracked from the moment it leaves the distributor's warehouse until it is delivered to the physician office. At no point does VaxCare take physical possession of the vaccines; however, it retains financial responsibility for the vaccines and pays all order invoices. VaxCare maintains insurance against loss of the vaccine product, including loss or damage caused by the physician office, and it will accept returns of unused vaccine. At the physician office, the vaccine products are stored in refrigerated units that are owned by the physician office and are not supplied by VaxCare.

#### VaxHub

The VaxHub is a proprietary hardware tablet and software technology that manages the vaccine inventory at the physician office, which is leased to the physician office for a fixed monthly fee. The VaxHub tablets are "locked" so that additional applications cannot be downloaded. VaxCare personnel place the VaxHub in the office of a contracting physician, typically on a stand near the physician's vaccine refrigerator, and train the physician's staff on its use. VaxHub installation is performed over the Internet, using the physician office Internet connection. VaxHub has a unique user log-in ID that is specific to each physician office. The VaxHub also has an integrated 1D/2D barcode scanner that allows the physician office staff to scan out any vaccine pulled from the refrigerator for purposes of administering the vaccine to a patient. Through the bar code scan, the VaxHub provides real-time decrementing of the inventory in the refrigerator. Upon hitting minimum inventory threshold levels set by the VaxCare algorithm, the VaxHub alerts the VaxBuy logistics platform to directly order additional vaccines. When the VaxBuy order arrives at the physician office, the VaxHub automatically increments the amount of inventory in its database. As required by many states, the VaxHub also reports all vaccine administration to a public registry.

# VaxPay

When patients come into the office for vaccination, the doctor's staff enters into the VaxPay portal the patient's demographic and insurance information as well as the immunization the patient

is scheduled to receive during the visit. The staff can access the VaxPay portal through the Internet on a desktop or laptop. The VaxPay portal requires a unique log-in to that provider office.

Upon entering the patient information and corresponding immunization into the VaxPay portal, VaxCare submits a front-end eligibility check prior to the submission of all claims. The real-time eligibility check determines if the patient's insurance is active and if the patient's insurance plan covers reimbursement for the proposed immunization.

If the eligibility check determines there exists an active insurance policy for the patient and the payer covers the proposed immunization, VaxCare classifies the vaccine as "Risk-Free" and assumes all risk associated with collecting reimbursement from the patient's payer. In this situation, VaxCare remits a fee to the physician for the physician office staff's performance of the administration; this fee generally is set at or slightly below the Medicare allowable payment in that region for administration of vaccine. If the eligibility check determines that the patient insurance is inactive or that the payer does not cover the proposed immunization, VaxCare classifies the vaccine as "At-Risk." In either case, the VaxPay system bills the payer for both the administration and vaccine according to CPT code billing guidelines. However, in the "At-Risk" situation, if VaxCare is later unable to collect reimbursement from the payer for the immunization, VaxCare charges the physician for the cost of the vaccine, and does not pay the physician for the performance of the vaccine administration.

# **Financial Summary**

The financial arrangement that exists between the doctor's office and VaxCare may thus be summarized as follows:

- As the billing provider of both vaccine and administration, VaxCare provides the physician office with the hardware and software platform used in the ordering and administration of vaccine, and trains physician staff on its use, at no separate charge;
- VaxCare purchases and assumes financial risk for the vaccine ordered for the physician office;
- The doctor pays his/her own staff to administer the vaccine; and
- VaxCare bills and collects under its own provider number for vaccine and administration, and remits a fee to the doctor for the doctor staff's performance of the administration; this fee generally is set at or below the Medicare allowable payment in that region for administration of vaccine.

#### III. ANALYSIS

### A. RHC and FQHC Billing under Medicare

RHCs are paid an all-inclusive rate ("AIR") per visit for certain enumerated primary health services and preventative health services (including influenza, pneumococcal, and hepatitis B

vaccines). Medicare calculates the AIR payment by taking the RHC's total allowable costs (which may include practitioner compensation, overhead, equipment, space, supplies, personnel) and dividing that number by the total number of patient visits at the RHC. The AIR is capped at a maximum amount that is set annually. Medicare pays 80% of the AIR, with the expectation that the RHC bills the remaining 20% to the patient as co-insurance. While FQHCs were previously paid in the same manner as RHCs under an AIR system, FQHCs are now paid through a prospective payment system ("PPS"). Under the FQHC PPS, Medicare pays 80% of the lesser of the FQHC's charge or the FQHC PPS payment rate, as adjusted by the center's geographic location and other factors, for the specific payment code.

Vaccines, however, are paid differently through RHC and FQHC cost reports (i.e., outside the AIR for RHCs and outside the PPS for FQHCs). RHCs and FQHCs provide three vaccines under Medicare: influenza, pneumococcal, and hepatitis B. Influenza and pneumococcal vaccines are paid at 100% of reasonable cost through the cost report. The cost report forms for the respective entities include worksheets used to calculate vaccine-related costs. For example, independent RHCs use Supplemental Worksheet B-1, while freestanding FQHCs use Worksheet B-

<sup>1</sup> Dep't of Health & Hum. Servs, Ctrs for Medicare & Medicaid Servs., Medicare Benefit Policy Manual, Ch. 13, Secs. 10 1: 50 1

<sup>&</sup>lt;sup>2</sup> The payment limit per visit is \$82.30 for calendar year 2017. Dep't of Health & Hum. Servs, Ctrs for Medicare & Medicaid Servs., Pub 100-04 (Medicare Claims Processing Manual), "Announcement of Payment Rate Increases for Rural Health Clinic (RHCs) for Calendar Year (CY) 2017," MM9829, Transmittal Number R3627CP, Change Request 9829, October 14, 2016.

<sup>&</sup>lt;sup>3</sup> Patient co-insurance is waived for certain stand-alone services, including influenza and pneumococcal vaccines . *See* Dep't of Health & Hum. Servs, Ctrs for Medicare & Medicaid Servs., Medicare Benefit Policy Manual, Ch. 13, Secs. 70.1.; 220.1.

<sup>&</sup>lt;sup>4</sup> Dep't of Health & Hum. Servs, Ctrs for Medicare & Medicaid Servs., Medicare Benefit Policy Manual, Ch. 13, Sec. 10.2.

<sup>&</sup>lt;sup>5</sup> Dep't of Health & Hum. Servs, Ctrs for Medicare & Medicaid Servs., Medicare Benefit Policy Manual, Ch. 13, Sec. 70.3. Patient co-insurance at FQHCs is also waived for influenza and pneumococcal vaccines. *See* Dep't of Health & Hum. Servs, Ctrs for Medicare & Medicaid Servs., Medicare Benefit Policy Manual, Ch. 13, Sec. 220.3.

<sup>&</sup>lt;sup>6</sup> 42 C.F.R. § 405.2466(b)(1)(iv) ("For RHCs and FQHCs, payment for pneumococcal and influenza vaccine and their administration is 100 percent of Medicare reasonable cost.") The third vaccine, hepatitis B, and its administration are included in the RHC or FQHC visit and are not separately billable. Dep't of Health & Hum. Servs, Ctrs for Medicare & Medicaid Servs., Medicare Benefit Policy Manual, Ch. 13, Secs. 220.1, 220.3.

<sup>&</sup>lt;sup>7</sup> Independent RHCs use Form CMS-222-92 to complete their cost report, while freestanding, skilled nursing facility-based, and home health agency-based FQHCs use Form CMS-224-14. *See* Dep't of Health & Hum. Servs, Ctrs for Medicare & Medicaid Servs., Independent Rural Health Clinic And Freestanding Federally Qualified Health Center Cost Report, Form CMS-222-92 (note that while the title of this form still mentions FQHCs, FQHCs can no longer use this cost report under the FQHC PPS); Dep't of Health & Hum. Servs, Ctrs for Medicare & Medicaid Servs., Federally Qualified Health Center Cost Report, Form CMS-224-14. Other provider-based RHCs and FQHCs should use the cost report forms for their respective provider types. *See* Dep't of Health & Hum. Servs, Ctrs for Medicare & Medicaid Servs., Hospital and Hospital Health Care Complex Cost Report, Form CMS-2552-10 (for hospital-based RHCs and FQHCs); Dep't of Health & Hum. Servs, Ctrs for Medicare & Medicaid Servs., Skilled Nursing Facility and Skilled Nursing Facility Health Care Complex Cost Report, Form CMS-2540-10 (for skilled nursing facility-based RHCs); Dep't of Health & Hum. Servs, Ctrs for Medicare & Medicaid Servs., Home Health Agency Cost Report, Form CMS-1728-94 (for home health agency-based RHCs). This memorandum's analysis focuses specifically on the cost reporting worksheets for independent RHCs and freestanding FQHCs under Forms CMS-222-92 and CMS-224-14; however, the conclusions apply equally to provider-based RHC and FQHC cost reports, which use virtually identical worksheets to calculate vaccine-related costs.

1 of their respective cost report forms.<sup>8</sup> On these two worksheets, the RHC or FQHC multiples total health care staff cost (calculated elsewhere in the cost report) times the ratio of the estimated percentage of time involved in administering pneumococcal and influenza vaccine injections in order to calculate direct vaccine administration cost. That is added to the cost of acquiring vaccine product to obtain total direct vaccine costs (the sum of administration and product cost). The worksheet then instructs the RHC or FQHC to divide the total direct cost by total RHC or FQHC facility direct cost (calculated elsewhere in the cost report) to obtain the vaccine percentage of the RHC's or FQHC's overlad cost (calculated elsewhere in the cost report) to obtain vaccine overhead. For example, if direct vaccine costs (the sum of administration and product) constitute 15% of an RHC's or FQHC's total direct costs, then vaccines would also be allocated 15% of the RHC's or FQHC's total overhead cost.

That allocation of overhead (the applicable percentage of total overhead attributable to vaccines) is then added to total direct vaccine cost to obtain the **total cost of pneumococcal and influenza vaccine and their administration**. In other words, this is the sum of vaccine administration and product costs, plus a fair allocation of RHC or FQHC overhead.

The calculations then separate out vaccines given to Medicare patients from vaccines given to non-Medicare patients. First, the **total cost of pneumococcal and influenza vaccine and their administration** is divided by the total number of all vaccine injections in order to obtain a perinjection cost.

That per-injection cost is then multiplied by the number of injections given to Medicare beneficiaries to obtain the "Total Medicare Cost of Pneumococcal and Influenza Vaccine and [Their] Administration."

This final amount is then paid in full by Medicare to the RHC or FQHC.<sup>9</sup> For RHCs, this amount is also subtracted out of AIR calculations.<sup>10</sup>

<sup>&</sup>lt;sup>8</sup> Instructions for Supplemental Worksheet B-1 of Form CMS-222-92 for independent RHCs state, "The cost and administration of pneumococcal and influenza vaccine to Medicare beneficiaries are 100 percent reimbursable by Medicare. This worksheet provides for the computation of the cost of the pneumococcal and influenza vaccines and their administration." Instructions for Worksheet B-1 of Form CMS-224-14 provide a nearly identical explanation for FQHCs.

<sup>&</sup>lt;sup>9</sup> For RHCs, this number is reported on cost report Form CMS-222-92, Worksheet C, Part II, which is used to calculate the payment due to the RHC. For FQHCs, this number is reported on cost report Form CMS-224-14, Worksheet E. Note that while the regulations state that vaccines will be reimbursed at "reasonable" cost, "reasonable" is not defined in the RHC or FQHC context or on the cost report. The cost report worksheets ask for actual costs. Subregulatory guidance, however, states that the Medicare Administrative Contractor who receives the cost report reviews the report for "productivity, reasonableness, and payment limitations." Dep't of Health & Hum. Servs, Ctrs for Medicare & Medicaid Servs., Medicare Learning Network, Rural Health Clinic, ICN 006398, January 2016, p. 5.

<sup>&</sup>lt;sup>10</sup> The cost report directs the RHC to subtract that amount from total allowable costs before dividing by number of patient visits to obtain the AIR. Dep't of Health & Hum. Servs, Ctrs for Medicare & Medicaid Servs., Independent Rural Health Clinic And Freestanding Federally Qualified Health Center Cost Report, Form CMS-222-92, Worksheet C, Part I.

While both RHCs and FQHCs are reimbursed for vaccine product and administration costs through the cost report, FQHCs are also instructed to report codes for vaccines and their administration in their regular claims process as well.<sup>11</sup> The reporting of such codes, however, is "for informational and data collection purposes only" and does not impact payment to the FQHC.<sup>12</sup>

#### B. RHC Billing When Contracting for VaxCare

You had asked whether RHC and FQHC billing of Medicare could potentially be duplicative of VaxCare's billing as a mass immunizer for vaccines and their administration. As noted above, influenza and pneumococcal vaccine product costs and their administration are not part of the RHC AIR and FQHC PPS, and in fact are explicitly subtracted out of AIR calculations. The RHC and FQHC must separately allocate and report all costs related to influenza and pneumococcal vaccines to receive payment. Thus, Medicare's AIR and PPS payment to the RHC and FQHC do not incorporate any time or cost related to acquiring or administering influenza and pneumococcal vaccines.

Analogously, when RHC and FQHC physicians contract with VaxCare to perform immunizations, for which VaxCare then bills Medicare as a mass immunizer (for both the vaccine and administration), the RHC's and FQHC's reports on total allowable costs should not include staff time and overhead spent administering vaccines on behalf of VaxCare, or the cost of acquiring vaccines, which is taken on by VaxCare. The RHC and FQHC would also not fill out Supplemental Worksheet B-1 or Worksheet B-1, respectively, to bill Medicare for the cost of administering influenza and pneumococcal vaccines, as this would be duplicative of VaxCare's billing. Similarly, the RHC and FQHC would not report costs for acquiring vaccine products, as VaxCare would be responsible for this. Moreover, the FQHC would omit reporting of vaccine administration codes in its claims for informational purposes to avoid any implication of duplicate payment.

Accordingly, as long as a contracted RHC or FQHC performs the same carve-out function for vaccine that it would be doing anyway, does not file Supplemental Worksheet B-1 or Worksheet B-1, respectively, and does not make any claims to any federal health care program for either the reimbursement of the cost or administration of any vaccines or for informational purposes, there would be no duplicative billing of Medicare for vaccine or administration through the VaxCare Model.

### C. RHC Commingling Restrictions

Another Medicare guidance relating to RHCs is also relevant to your inquiry. The Medicare Benefit Policy Manual (the "Manual") prohibits what is known as "commingling," which refers to "the sharing of RHC or FQHC space, staff (employed or contracted), supplies, equipment, and/or other resources with an onsite Medicare Part B or Medicaid fee-for-service practice *operated by the* 

<sup>&</sup>lt;sup>11</sup> Dep't of Health & Hum. Servs, Ctrs for Medicare & Medicaid Servs., Medicare Claims Processing Manual, Ch. 9, Secs. 60.2, 60.3; 70.4. *See also* Dep't of Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., Medicare Benefit Policy Manual, Ch. 13, Sec. 220.3 ("FQHCs must include these charges on the claim if furnished as part of an encounter.").

<sup>&</sup>lt;sup>12</sup> Dep't of Health & Hum. Servs, Ctrs for Medicare & Medicaid Servs., Medicare Claims Processing Manual, Ch. 9, Sec. 70.4. *See also Id.* at Secs. 60.2, 60.3

same RHC or FQHC physician(s) and/or non-physician(s) practitioners." <sup>13</sup> The Manual further explains the commingling rule by noting that "RHC and FQHC practitioners may not furnish or separately bill for RHC or FQHC-covered professional services as a Part B provider in the RHC or FQHC, or in an area outside of the certified RHC or FQHC space, such as a treatment room adjacent to the RHC or FQHC, during RHC or FQHC hours of operation. If an RHC or FQHC practitioner furnishes an RHC or FQHC service at the RHC or FQHC during RHC or FQHC hours, the service must be billed as an RHC or FQHC service. The service cannot be carved out of the cost report and billed to Part B."<sup>14</sup>

Under the VaxCare Model, the physicians and their staffs at the RHC or FQHC are not operating an onsite Medicare Part B practice, nor are they "furnishing" or "separately billing for" the vaccine. Instead, VaxCare is the Part B provider, and the RHC or FQHC physicians are contractors to VaxCare. VaxCare is furnishing, and billing for, the vaccine and its administration. As such, it is reasonable to conclude that the VaxCare Model does not fall within the Manual prohibition on commingling.

A further reason to conclude that the commingling prohibition does not apply is that the VaxCare Model does not run afoul of the rationales provided by Medicare for the commingling prohibition. Medicare provides two rationales for the prohibition on commingling: "[c]ommingling is prohibited in order to prevent [i] [d]uplicate Medicare or Medicaid reimbursement (including situations where the RHC or FQHC is unable to distinguish its actual costs from those that are reimbursed on a fee-for-service basis), or [ii] [s]electively choosing a higher or lower reimbursement rate for the services." <sup>15</sup>

The first concern is to prevent duplicative reimbursement, including where the RHC or FQHC is unable to distinguish its actual costs. However, as explained above, this should not occur under the VaxCare Model, because the process the RHC or FQHC uses to separate out VaxCare-related costs is the same process it uses to separate out the cost of the vaccine product and its administration on the cost report to be directly reimbursed by Medicare. Because the RHC or FQHC is using the same method whether they report directly or contract for VaxCare, the RHC or FQHC should have no difficulty ensuring that vaccine-related costs are not reflected in its allowable cost, or included in the applicable worksheet.

The second concern relates to choosing a higher reimbursement rate for the services. <sup>16</sup> Again, this should not occur under the VaxCare Model. Medicare could reasonably be concerned with RHC or FQHC physicians contracting with VaxCare if, as a result, Medicare pays a higher reimbursement rate for the same vaccine and administration. In this case, the two reimbursement rates in question would be the reimbursement rate to VaxCare, as a mass immunizer, versus the reimbursement rate to the RHC or FQHC, as calculated on the RHC's or FQHC's cost report. As

<sup>&</sup>lt;sup>13</sup> Dep't of Health & Hum. Servs, Ctrs for Medicare & Medicaid Servs., Medicare Benefit Policy Manual, Ch. 13, Ch. 13, Sec. 100 (emphasis added).

<sup>&</sup>lt;sup>14</sup> *Id.* (emphasis added).

<sup>&</sup>lt;sup>15</sup> *Id*.

<sup>&</sup>lt;sup>16</sup> The reference to a "lower" reimbursement rate seems intended just for completeness. Obviously, Medicare's concern is that an RHC would manipulate its billings to obtain *higher* reimbursement.

discussed, RHCs and FQHCs are reimbursed based on actual cost. Mass immunizers, like most other Part B suppliers, are reimbursed according to the Medicare Physician Fee Schedule ("MPFS").

Without information showing an RHC's or FQHC's actual costs, it is not possible to do a direct comparison with Medicare reimbursement rates. However, there are good reasons to believe that Medicare reimbursement of an RHC's or FQHC's costs for vaccine services generally would be higher, and certainly not lower, than VaxCare's MPFS reimbursement.

First, Medicare arrives at the MPFS amounts based on national data on practice expenses, adjusted for regional differences.<sup>17</sup> As discussed above, this is very similar to the methodology used by Medicare to calculate vaccine reimbursement.<sup>18</sup> Accordingly, the starting point for comparison should be that the Medicare physician fee schedule payment and a payment derived based on a regular physician's practice costs should be very close in a given geography.

Second, in recognition of the fact that obtaining health care in rural and other underserved communities is more difficult, *Congress has long provided RHCs and FQHCs with more favorable reimbursement* than most Medicare Part B suppliers. For example, when Congress adopted the RHC Amendments of 1977, it provided that RHCs would be reimbursed on the basis of the RHC's reasonable costs in furnishing care to Medicare and Medicaid beneficiaries, in contrast to the standard Medicare Part B reimbursement methodology at the time which provided for reimbursement based on the more closely-regulated standard of reasonable charges.<sup>19</sup> The history of cost-basis reimbursement is that, because it provides incentives for higher costs, it generally results in higher reimbursement than other payment methodologies and, accordingly, Medicare largely abandoned cost-basis reimbursement in the 1980s.<sup>20</sup> However, as discussed above, Medicare

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<sup>&</sup>lt;sup>17</sup> The actual formula takes into account the value of the physician's work, the expenses of the practice (primarily staff time, supplies and overhead) and what is usually a very small component for malpractice insurance. In the case of vaccine services, there should be no physician work component, so the fee schedule amount would be based largely on staff time and overhead. Dep't of Health & Hum. Servs, Ctrs for Medicare & Medicaid Servs., 2012-2013 Immunizers' Question & Answer Guide to Medicare Part B, Medicaid and CHIP Coverage of Seasonal Influenza and Pneumococcal Vaccinations, Section C (Payment Policy). *See also* Dep't of Health & Hum. Servs, Ctrs for Medicare & Medicaid Servs., Medicare Learning Network, "Medicare Physician Fee Schedule," ICN 006814, February 2017.

<sup>&</sup>lt;sup>18</sup> An RHC's or FQHC's cost for administration is to be calculated by staff time multiplied by staff cost, plus the RHC's or FQHC's applicable overhead percentage, as described in more detail in Section III.A, *supra*.

<sup>&</sup>lt;sup>19</sup> See, e.g., H. Rep. Rept. No. 95-548, Part II, 95<sup>th</sup> Cong. 1<sup>st</sup> Sess. (Sept. 19, 1977) at 6 ("committee believes that by providing for reimbursement on the basis of costs incurred in furnishing covered services . . . the bill addresses the existing problem of lack of full-time physician services in such areas in a cost effective and efficient manner.") and at19 (creating reasonable cost reimbursement for RHCs (as defined in Section 1832(a)(2)(D)) under new section 1833(a)(3) of the Social Security Act, in contrast to the reasonable charge methodology provided for other Part B medical and other health services under Section 1833(a)(1) of the Act). Today, the contrast is likely to be even greater, since as a cost-containment measure, Medicare has replaced reasonable charge reimbursement with the MPFS. Likewise, prior to the Affordable Care Act's transition of all FQHCs to a prospective payment system in 2016, FQHCs were reimbursed in the same manner as RHCs. See 42 U.S.C. § 1395l(a)(3). As discussed in Section III.A, supra, while FQHC reimbursement has since transitioned to the FQHC PPS, vaccines continue to be reimbursed through FQHC cost reports.

<sup>&</sup>lt;sup>20</sup> See, e.g., 3 Legislative History of the Social Security Act of 1983 P.L. 98-21 97 Stat. 65 H965 (1983) (under cost reimbursement, "there is little or no incentive to control costs or operate efficiently . . . [and the proposed prospective payment system, in contrast] will provide long needed economic incentives for hospitals to be efficient and cost-conscious in the delivery of care to [M]edicare beneficiaries.") (Statement of ranking member).

has retained cost-basis reimbursement for vaccines with respect to RHCs and FQHCs. It would be anomalous to say the least if vaccine reimbursement to an RHC or FQHC were to depart from both of these principles: that cost-basis reimbursement is generally higher than other reimbursement methodologies, and that RHCs and FQHCs have been designed to occupy a favored reimbursement position.

For both of these reasons, it seems reasonable to conclude that Medicare payment for vaccines provide through VaxCare would *not* exceed payment that would otherwise be provided to an RHC or FQHC, and thus that the VaxCare Model would not implicate the higher reimbursement concern underlying Medicare's commingling prohibition.

# IV. CONCLUSION

Our conclusion is set forth in the Executive Summary on p. 1, supra.

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We hope this information is useful to you. If you have any questions, or if we may be of any further assistance, please do not hesitate to give us a call.