Department of Health and Human Services
Centers for Disease Control and Prevention

On September 12, 2006, the Centers for Disease Control and Prevention (CDC) selected McKesson Specialty Distribution as the vaccine distributor of choice for the National Center for Immunization and Respiratory Diseases' (NCIRD) Vaccines for Children Program (VFC).

This is an exciting time and we anticipate questions from our grantees and partners. Below are the questions compiled from the Program Managers' Meeting in December 2006 and the second round of FAQs. We will continue to send out the FAQs as long as there are additional questions or updates to previous answers. If you have any follow-up questions, please contact your project officer. Thank you!

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1. **Why did only one company get the contract when there was a possibility of multiple awards in the event that one company went under or had some other unforeseen circumstance?**
   This section of the RFP reads as follows:
   "CDC intends to award the centralized distribution contract to one to three Contractors. It is expected that, if the distribution and storage contract is awarded to more than one vendor, the stockpiles will be split among the vendors in proportion with the percentage of the national vaccine demand awarded."

   The intention was to award the contract to at least one company with the possibility of awarding the contract to two or even three companies. These were options, but not requirements.

2. **Has the pre-award protest been resolved?**
   Yes, the pre-award protest has been resolved. The Government Accountability Office (GAO) ruled in favor of the CDC on November 15, 2006. All three protests were resolved at that time.

3. **From where will the centralized distributor ship and will there be other central distributors that represent other regions (East, West, etc) of the US?**
   McKesson has been selected as the vendor for the entire U.S. Currently, McKesson will be shipping from Memphis, TN. Additional facilities will be added at a later date.

4. What is the delivery price per dose the new contractor quotes in the contract?

The distribution contract is available via FOIA request. Please work with your AIM representative to obtain a copy.

5. Are there any particular dates or months when the centralized distributor will not be able to ship vaccines (i.e. the week of Thanksgiving, month of December)?

McKesson will be open all year around except for national holidays. These holidays include:

Holidays - Government personnel observe the following listed days as holidays:

Washington's Birthday
Memorial Day
Independence Day
Labor Day
Veterans' Day
Thanksgiving Day
Christmas Day
New Year's Day
Columbus Day
Martin Luther King Day

Any other day designated by Federal Statute
Any other day designated by Executive Order
Any other day designated by Presidential proclamation

Unscheduled Facility Closures

In the event the Government facilities are closed due to inclement weather, potentially hazardous conditions, and other special circumstances, contractor personnel assigned to work within those facilities are automatically dismissed. In each instance, the Contractor agrees to continue to provide sufficient personnel to perform round-the-clock requirements of critical tasks already in operation or scheduled, and shall be guided by the instructions issued by the Contracting Officer or his duly appointed representative.

6. For emergency orders/situations:

6a. How will the centralized distributor handle emergency orders/situations?

Providers may request vaccines on a priority basis. Upon receiving a priority provider order from the Project, McKesson shall:

a) Expedite its pick, pack, and shipment by placing it ahead of other routine orders and by choosing a faster shipment method (i.e. overnight). Orders received shall be processed by McKesson within one business day of McKesson's receipt of the orders.

b) Choose a shipment mode that will guarantee that the vaccine will arrive in viable condition.

c) Work with the Project Point of Contact (PPOC) to arrange for receipt of the shipment on a Friday or Saturday if desired and if the provider will be available to receive the shipment.

7. If there are SOPs, will they be shared with Grantees?

No. Proposed changes to the SOPs shall be provided to the CDC Contracting Officer and the CDC Project Officer for comment.

8. What is the expected delivery timeframe of orders?

McKesson will abide by the following regulations in regards to shipment of orders:

a) McKesson shall ship orders such that the first delivery attempt will fall within the acceptable shipment times as identified by the provider.
b) McKesson shall process each order so that the time between order receipt and order shipment meets the following requirements:
    a. 80% of orders shipped within three shipping days
    b. 100% of orders shipped within five shipping days
c) McKesson shall choose a mode of shipment whose total in-transit time does not exceed 48 hours except for the Pacific Island Projects whose total in-transit time does not exceed 60 hours.

9. How will the centralized distributor monitor and manage the caps on the quantity of vaccines states can order?

McKesson will also be given the total amount that each grantee is allowed to order. How the vaccine is distributed among the individual providers is up to the grantee.

The spend plan will also be used in monitoring the vaccines that are in shortage. Grantees will be monitored against what is stated in the spend plan and the actual orders that are distributed to each provider. Once orders for a specific project reach the dose cap, orders will be held by the distributor until additional vaccine is available for that project.

10. What will happen if that ordering threshold is approached or breached?

Grantees will be notified of their allocation for vaccines on shortage. McKesson will also be given this vaccine allocation for each grantee. Once the vaccine allocation has been distributed, there may be a short or long term delay for additional fulfillment of provider orders depending on how severe the vaccine shortage is.

11. Will the grantees be involved with the monitoring or management of caps on the amount of vaccines states can order?

Yes, grantees will receive month-to-date reports that are detailed to the antigen level from their project officer. This will provide weekly information on each antigen. As stated above, it is up to the grantee to manage a shortage vaccine at the provider level.

12. The RFP reads that total transit time to the Pacific Island projects shall not exceed 60 hours. How will the centralized distributor meet this obligation to deliver to the Hawaiian and Pacific island projects?

Vaccines distributed to providers in the six Pacific Islands (Samoa, Micronesia, Guam, Marshall Islands, N. Mariana Island and Palau) will continue to be dropped off at a central depot or airport in each of the islands.

13. How will a depot service Hawaii and other island grantees?

FedEx Direct priority overnight, 1-2 day service to the islands

14. It's our understanding that McKesson plans to ship vaccine to Hawaii using commercial carriers. (I believe that this would apply to Puerto Rico and the US Virgin Islands as well.) We understood that you were still finalizing your approach for servicing the other island grantees. It might be helpful if your response references any previous shipping experience you have with regard to the island grantees, particularly of temperature-sensitive products

FedEx International Priority provides a seamless process and door to door service, 1-3 day guarantee. Tracking capabilities throughout process with pre-notifications on all shipments, with emergency refrigeration capabilities if needed.

15. How does McKesson plan to incorporate each provider's operating hours/information into their order fulfillment process?

Currently, grantees save provider delivery instructions on VACMAN in a notes field. The standard adoption will require grantees to manually update individual provider shipping information in VACMAN and include provider open days and special shipping instructions.

16. Does McKesson have a format preference that the information is delivered to them via NIPVAC?

The McKesson format preferences are as follows:

1. Times listed should be OPEN only

2. Standard open times are Monday thru Friday 9 am to 5 pm

3. If text field is completely empty assume standard open times apply

4. Format for days of the week are:
    a. Monday = M
    b. Tuesday = T
    c. Wednesday = W
    d. Thursday = TH
    e. Friday = F

5. All open days are separated by a comma = ","

6. A semi-colon (";") will follow the open days to separate the days from special shipping instructions

7. Hours of operations to be included in the special shipping instructions

17. What is McKesson's experience with vaccine shipping?
They ship over 1,000 cold chain packages per day. Vaccines have been part of their product mix for the last several years servicing oncology accounts and physician offices. McKesson is one of the largest distributors of vaccines in the US.

18. Rollover vaccine: Recognizing that forecasting is an inexact science; would it be possible to build in a margin of plus or minus 5 to 10 percent as a buffer? If providers order 10 percent under estimate, the 10 percent will be rolled over automatically to the next period, without modification of the spend plan. A prudent project will want to plan for a little extra, without penalty. Provider over-orders of up to 10 percent would likewise be absorbed without changing the spend plan.

Under centralized distribution there will be a 10 percent year-to-date buffer. Aggregate vaccine orders from grantee providers may be up to 10 percent year-to-date above or below spend plan before any intervention by CDC (such as requesting a spend plan update). Under the current monthly allocation or inventory transition protocols, vaccine orders may be approved above allocation if there is an unanticipated, unplanned for, need which would result in the grantee not having adequate vaccine to meet their needs. Because vaccine doses not ordered in one month are not necessarily needed the next month as supplements to spend plan amounts, automatic "rollovers" cannot be considered. Careful completion of spend plans and inventory transition tool would eliminate most vaccine ordering issues.

19. Who dictates how much vaccine we can order every month – shouldn't that decision be made by us along with our project officer?

Vaccine orders should be placed in accordance with the monthly vaccine allocation or inventory transition amounts. These amounts derive from grantee provided data. For grantees on monthly allocation, the data includes end of month inventory, current purchases (orders placed but vaccine not yet in inventory) and spend plan identified three-month need. For grantees on inventory transition, the data is the product (amounts) of the grantee-completed inventory transition tool. Vaccine orders may be approved above allocation if there is an unanticipated, unplanned for, need which would result in the grantee not having adequate vaccine to meet their needs. Approval, or denial, is only made by NCIRD staff. Contractor staff only provide data collection and analysis support.

20. How will the spend plan become more flexible?

Moving forward, the main flexibility of the spend plans will be one of access through the vaccine ordering and distribution system (VODS). Additionally, historical information captured by VODS will allow grantees to more accurately determine seasonality adjusted need.

21. Why is it that with MCV4 states who had reached their allotted cap were not allowed to exceed their cap when other states weren't using all their allotment – shouldn't those doses have been reallocated?

Approval of MCV4 orders occurred on an order-by-order basis contingent on available supplies.

22. While it is good to hear the current VACMAN will be replaced for some projects with VACMAN 4.0 and some projects will transition directly to VODS, support for the current version of VACMAN is vital. Can you address assurances for current support of VACMAN since many projects have voiced concerns and problems with VACMAN support from CDC?

The CDC will provide support for the current version and VACMAN 4.1 for the entire time they are in production.

23. Will projects that use their registries for providers to order vaccine be interfaced with VODS?

Yes, VODS will provide a standard messaging interface to external information systems; this would include registries and other systems.

24. What are the specific requirements of VODS? When will VODS be available?

The VODS requirements comprise a full set of system and business requirements a copy of which has been provided to AIM. The timeline will be determined based on finalizing the FMO requirements and setting up user groups with AIRA and AIM.

25. Have any of the business rules changed? It is safe to assume that the business rules (e.g., reporting inventory on hand) won't change prior to transitioning to VMBIP ordering processes?

The VMBIP/VODS leadership team has setup a "Change Control Board" (CCB) to review any changes to any VODS requirement.

26. What will reports to grantees look like?

The format for VODS is still pending; VACMAN is the same as today

27. What will be the report frequencies?

Depends on the report; ad hoc reporting will be in the system.

28. What will be the report formats?

The format for VODS is still pending; VACMAN is the same as today

29. How will the influenza vaccine supply and distribution be planned and implemented? Will the supply include all influenza vaccine formulations?
Grantees will continue to order influenza vaccine as it is currently ordered. The centralized distribution model will include both vaccines purchased through the federal contract and vaccines purchased through non-federal contracts (Project contracts) for all 64 Projects.

30. How will vaccine wastage be reported, by whom? (If we dismantle our in-house shipping facility, we cannot be expected to process wasted vaccine supplies.)

Providers will return all non-viable vaccine directly to McKesson. McKesson will return all non-viable vaccine returned to the Manufacturers for excise tax credit.

31. What is the interim data warehouse? How will it meet our needs? How do we use it to generate data/reports?
A one page overview of reporting sources and frequencies is being developed. Once that has been completed it will be distributed to all grantees.

32. How will the state's/grantee's inventory be guaranteed by the distributor?
Vaccines purchased through Project contracts (non-federal) will be held in a single physical inventory, with Project-specific virtual inventory tracking and reporting.

33. Can we tell our providers that their orders will be shipped within 5 days? Define 5 days.
McKesson will accept orders Monday through Friday excluding Federal Holidays. 80% of orders will be shipped within 3 shipping days and 100% will be shipped within 5 shipping days.

34. Will McKesson hire staff that will deal only with VFC/317 vaccine orders? Who will train staff about vaccine shipping?
McKesson is required to maintain written Standard Operating Procedures regarding training, storage, receiving, packing, shipping, and returns. Standard Operating Procedures will be approved by CDC prior to implementation. The training of personnel will include all employees who primarily work on the Vaccine Distribution Contract as well as any employees who might be used as back-up. McKesson will conduct in-house trainings and will maintain records of training of employees.

35. Our state transferred distribution from Bellco to GIV. When we did this, we went to GIV to observe their distribution process, met with staff – this was helpful in answering questions from providers, establishing working relationships with GIV. Will McKesson consider letting grantees do this?

Yes, it is the intent of both CDC and McKesson to offer an open house to grantees to view the distribution site. The date for the Open House in Memphis is April 18, 2007.

36. Will McKesson staff be at NIC to answer questions from VFC Coordinators and others not at the program managers meeting?

Yes, McKesson will have a representative at NIC to answer questions from VFC Coordinators and others.

37. Will CDC coordinate with states to help renew contracts?
Yes, CDC will assist in this process although it is the responsibility of the state to renew its contract.

38. Please explain the overall evaluation plan and the metrics?
The overall evaluation plan includes conducting a pre and post evaluation of centralized distribution. Our aim is to compare certain aspects of the program prior to and after grantees have transitioned to centralized distribution. In order to focus this evaluation on specific elements (e.g. customer satisfaction) we developed a list of evaluation metrics. As data is collected against these metrics we will be able to analyze it and determine the overall impact of the programmatic improvements.

39. How will non-baseline evaluation metrics be reported to the grantee?
Data derived from non-baseline evaluation metrics will be reported to the grantees with the other data. We do not anticipate sending information piecemeal, but rather compiling all the data into a comprehensive report and providing that to grantees. Updates, which are projected to be quarterly, will be communicated as new data is generated.

40. **How will customer service metrics be collected and reported?**
Customer service metrics are defined in the contract and serve to measure the effectiveness and efficiency of the vaccine distributor. We have specific mechanisms written into the contract and the VMBIP Evaluation team will collect the data on those metrics. Our communications team has committed to circulating a VMBIP newsletter every two months to update grantees on the progress of the pilot period, recent transitions, and overall VMBIP updates. We can use this as a means of reporting customer service data. Please be assured we will share data with grantees as often as it can be collected and analyzed. For those times when we rely on grantees to provide data we encourage you to provide it in a timely manner so we can analyze it quickly and provide you with the results.

41. Will adequate time be planned for the evaluation of the pilot projects and will system changes be made based on the evaluation prior to roll-out to other projects?

The revised roll out schedule includes a 12 week pilot period. This provides ample time to gather data on the pilot grantees' experiences and make modifications as needed.

42. What will CDC do with the evaluation data? Will it be passed on to the distributor?

The evaluation data will be used to modify and/or improve the centralized distribution and grantee roll on process. It also provides a go/no-go decision for CDC. If there are serious challenges we can pause, make changes, and move forward successfully. The distributor will receive data that is specific to their needs. For example, if providers report their vaccine shipments are arriving in a timely manner, McKesson can use this data to maintain their processes.

43. With regard to the Provider survey, do you want projects to sample all the providers each quarter? Will the distributor do this?

Providers will have the opportunity to provide feedback via "comment cards" included in each vaccine shipment. Responses will be anonymous but providers are asked to include their zip code so we can group the responses by geography and ensure the data are not skewed by volume and frequency of provider orders. It is anticipated each card will take 30-60 seconds to complete and will be targeted to the person(s) unpacking the shipment boxes. This provider evaluation plan is still being finalized so we welcome your feedback.

44. What is the end point for the baseline evaluation?

The baseline evaluation establishes a current state for the VMBIP effort. Each grantee, including pilots, will have an opportunity to provide baseline information. The end point is therefore when all grantees have transitioned to centralized distribution and finished their quarterly updates.

45. Regarding the analysis plan for the evaluation, are the evaluations being conducted state by state or nationally? Are you looking at problems across states?

We will initially group the data according to distribution type (e.g. in house, third party, and hybrid). We understand and agree that state to state comparisons or possible geographic comparisons may provide a more comprehensive understanding of the impact centralized distribution has had on specific grantees. If there are other ways that grantees would like to see data analyzed or have specific data needs, we encourage you to contact our evaluation team.

http://www.cdc.gov/vaccines/programs/vmbip/downloads/distributor-faq2.pdf