Invitation for Bid # C041106

Naloxone and Fentanyl Strip Overdose Prevention
Questions and Answers – Posted June 5, 2025

Question Number	QUESTION	ANSWER
1	Would a program that does not itself manufacture naloxone, but has many years of experience with obtaining government and competitive pricing for naloxone, widespread, very high-volume, Statewide distribution of naloxone and test strips (>21 million test strips distributed) and also integrates with UPS and utilizes an efficient and electronic ordering, labeling, and shipping process quality for this opportunity?	No, per Section 3 Minimum Qualifications to Bid, the IFB states that the Bidder must have a minimum of two (2) years of experience manufacturing, direct shipping, distributing, and tracking a high volume (est. 45,000 per month) of opioid antagonist of the naloxone classification shipments to the requestor. In order to qualify for this opportunity, you must be a manufacturer of naloxone.
2	Would there be any reason we cannot bid on this business? Do all bidders need to be minority/women owned businesses?	Please refer to Section 3.0 of the IFB that outlines the minimum qualifications. If a bidder meets all of the minimum qualifications, the bidder is eligible to submit a proposal in response to this IFB. No, a Bidder need not be a minority-or woman-owned business to be eligible to bid.
3	Would the State be willing to adjust the requirements at Pg. 6 to afford distributors to respond?	Please refer to Section 3.0 of the IFB that outlines the minimum qualifications. If a bidder meets all of the minimum qualifications, the bidder is eligible to submit a proposal in response to this IFB.
4	What would be the minimum requirements to try to open this up to authorized distributors of opioid antagonists of the naloxone classifications who generally have experience with distribution of this product type?	This solicitation is not for distributors. Please refer to Section 3.0 of the IFB that outlines the minimum qualifications. If a bidder meets all the minimum qualifications, the bidder is eligible to submit a proposal in response to this IFB.

5	This IFB references providers of injectable naloxone in several places (3.1, p4 & 6.1.2, p13), however, the bid form (p21-22) does not have a place to bid for injectable naloxone- is this naloxone IFB exclusively for nasal naloxone? If yes, does the Department plan to release a separate IFB for injectable naloxone?	The bid is specifically for nasal naloxone only. The references made to injectable naloxone are specific to the minimum qualifications section that states: The Bidder must have two years' experience providing a Food and Drug Administration (FDA) approved intranasal naloxone variation 4mg in a 0.1 mL solution or injectable naloxone single use. This is specific to experience only. There is no solicitation for injectable naloxone that is forthcoming at this time.
6	Section 3.1 Mandatory Qualifications, bullet #1, "The Bidder must have a minimum of two (2) years of experience manufacturing, direct shipping, distributing, and tracking a high volume (est. 45,000 per month) of opioid antagonist of the naloxone classification shipments to the requestor," suggests that the current bid opportunity is only open to the vendor currently providing naloxone to the Department. Our company has an extensive track record of successfully manufacturing, direct shipping, distributing, and tracking a high volume of products, including naloxone. We have demonstrated our ability to successfully fulfill a comparable contract in another state. Please define who "the requestor" is referenced in Section 3.1, bullet #1. Will the Department consider making this procurement open to more than one vendor by considering responses from suppliers not currently contracting with the Department to provide naloxone?	Requestor in this section references anyone who was requesting naloxone, it does not need to be DOH. For example, if your company has been fulfilling other contracts at the volume outlined in the IFB that outside company is the requestor. The Department will only be contracting with one manufacturer.
7	Section 3.1 Mandatory Qualifications, bullet #2, "The Bidder must have two years' experience providing a Food and Drug Administration (FDA)	The Bidder must have two years' experience providing a Food and Drug Administration (FDA) approved intranasal naloxone variation 4 mg in a 0.1 mL solution or injectable naloxone single use.

	approved intranasal naloxone variation 4 mg in a 0.1 mL solution or injectable naloxone single use," suggests that the Department has a preference for the brand manufacturer and is excluding capable generic manufacturers from receiving a fair bid opportunity. Generic manufacturers provide affordable access to medicines and help drive down the costs of medicines. Generic drugs typically have a delayed introduction into the market compared to branded products due to the exclusivity period granted to the brand name manufacturer. Our company changed the pricing landscape of naloxone when we entered into a partnership with another state to offer affordable naloxone throughout the state. Generic competition drives down prices and increases access for patients. Will the Department consider generic manufacturers with less than two years of experience providing an FDA-approved naloxone nasal spray HCl, 4 mg, if the supplier can demonstrate successful performance for a comparable volume contract across any product? Recognizing that generic manufacturers drive down costs, if not, why not? Why is two years selected as the requirement for experience?	Generic manufacturers would be acceptable as long it is FDA approved and meets the two years experience as listed in the minimum qualifications.
8	Per New York State Finance Law 163(2), the state promotes procurement fairness. Limiting suppliers to only those with experience with the Department is not a fair procurement practice. It is also not a fair procurement practice to put generic manufacturers at a time disadvantage	There is no exclusion for generic manufacturers. The minimum qualifications for bidding in Section 3.1 state that the experience of two years must be with a requestor for naloxone, that does not mean the Department directly. The other minimum qualifications relate to the type of product, which needs to be naloxone, and the

	for offering an equal, but more affordable product that is subject to FDA processes and approvals for introduction to the market. Our company is an experienced pharmaceutical manufacturer and distributor with a stellar reputation for quality. We have proven experience providing comparable work on a larger scale for another state. We also support New York's economy with one of the largest domestic generics pharmaceutical manufacturing facilities by total scripts in the U.S. Please explain how this bid meets the New York State Finance Law 163(2) requirements regarding "fairness in contracting," given that the mandatory qualifications appear to exclude generic manufacturers.	requirement of a shipping contract. Generic manufacturers that meet these qualifications are encouraged to apply.
9	Section 3.1, bullets #1 and #2 do not support fair procurement/contracting practices. It is also unclear why a full two years of experience providing intranasal naloxone or injectable naloxone is a mandatory qualification to demonstrate performance. Generic manufacturers have less time in the market compared to branded manufacturers but offer an equally effective product with comparable wrap-around service. They also have experience with other pharmaceutical products. These mandatory qualifications discourage generic entrants, limit competition, and potentially increase pricing for the Department at a time when budgets are especially tight and scrutinized, and resources are being cut from	As stated in Section 3.1 of the IFB the requestor can be with another state or customer, but the bidder must have the two years' experience with naloxone as it relates to these other contracts. As outlined above, the Department felt two years' experience (bullet 1 & 2) was needed to satisfy the need for the manufacturer to demonstrate sufficient experience with product development, volume control, and shipping.

	the Federal government for public health programs. Would comparable performance with another state (or customer) be considered acceptable evidence of experience? Please explain how the Mandatory Requirements referenced in Section 3.1 (bullets 1 and 2) are necessary minimum requirements to identify a qualified, responsive supplier.	
10	Is it required to ship both Naloxone and Fentanyl Test Strips in the same package? Or can they be shipped separately?	Naloxone and FTS can be shipped separately. As stated in the IFB, Section 4.2., the fentanyl testing strips must be shipped concurrently with the shipments of naloxone ordered by registered programs.
11	Is the state open to price changes given the uncertainty in the current landscape of trade agreements between many countries and the US?	The price that is quoted in the bid is the price that would be in effect throughout the contract period. On Attachment B, Bidders are instructed to confirm their agreement with the following, "The price charged to the Department must always be equal to the lesser of year one pricing or the then current Federal Supply Schedule price. While there is no Federal Supply Schedule Pricing in place for FTS, the expectation from the Department is that the price charged for FTS must be equal to or less than what was outlined in the bid.
12	Does the State plan to process one PO for both Naloxone and Fentanyl Test Strips? Or will there be two PO's?	The Department would process two separate Purchase Orders (POs).
13	Is the State looking for a single supplier, or does the State plan on using more than one supplier for Naloxone?	Per Section 2. Overview: It is the Department's intent to award one (1) contract from this procurement.

14	Can you provide estimates on monthly quantities for Fentanyl Test Strips? How many will be ordered in year 1? and year 2?	Per Section 4.2, the number of testing strips is determined by the program and can range anywhere from 0-1,000 strips per order of naloxone. At this time there is no projection available. This is a new service and legislative directive. The Department is unclear on the volume.
15	When does the State anticipate requesting the first order to be shipped?	The new contract is projected to begin 12/1/25 and shipping of both products would need to occur one week after contract execution. See Amendment #1.
16	What is the lead time (lag time) between PO and requested delivery date?	The Department expects POs to be submitted bi-weekly for both Fentanyl Test Strips (FTS) and naloxone.
17	Is there a minimum order quantity for Fentanyl Test Strips?	There is no minimum order for Fentanyl Test Strips (FTS) in place.
18	Per Section 3.1 Mandatory Qualifications – A sole shipping contract is reasonable, but suppliers should have the ability to establish redundancy in shipping methods. Will the Department allow suppliers to have a primary shipping company with additional redundant/contingent shipping contract(s)?	The Department is requiring that one shipping vendor be utilized for naloxone and FTS shipping. Multiple shipping contracts will not be accepted.
19	Certain requirements of the RFP deal with EEO and diversity initiatives, such as Sections 4.10 and 4.11. Our organization maintains an EEO policy and recognizes the value of diversity in its workforce. Section 4.11 references Attachment 8 which states, at Section 12 (EEO clause) as follows: “The contracting agency shall determine whether the imposition of the requirements of the provisions hereof duplicate or conflict with any such federal law and if such duplication or conflict exists, the contracting agency shall	The DOH reserves the right to negotiate with the successful bidder. However, bidders acknowledge and accept all provisions as evidenced by their signature on Attachment 7.

	waive the applicability of Section 312 to the extent of such duplication or conflict." Given current Executive Orders, including but not limited to EO 14173, may conflict with certain requirements of the RFP, will any requirements of the RFP be waived given such conflicts?	
20	Per Section 4.2 Bid and Product or Service Requirements, the requirements state that, "The fentanyl test strips must be shipped concurrently with the shipments of naloxone ordered by registered programs." Please clarify how the Department wants fentanyl test strips packaged. Do fentanyl test strips need to be shipped in the same outer box with naloxone (i.e. one outer box that contains both units of naloxone and individually packaged fentanyl test strips) or will the strips be an external add-on per shipment (i.e. one box containing naloxone units and a separate package containing fentanyl test strips)?	The fentanyl test strips are not required to be shipped in the same box as naloxone. The fentanyl test strips may be shipped in a separate shipment and packaged as the vendor and contracted agency agree.
21	Regarding Section 4.2 Bid and Product or Service Requirements – Many harm reduction programs distribute fentanyl test kits to help facilitate the testing process. Pricing varies between fentanyl test strips and fentanyl test kits (kits include a swab or scoop and may include a vial with water to conduct the test). Is the Department seeking quotes for only fentanyl test strips and not fentanyl test kits?	The Department is only seeking quotes for fentanyl test strips. Fentanyl test strips kits are not part of this IFB.

22	Regarding Section 4.2 Bid and Product or Service Requirements – Can you provide any data for the anticipated fentanyl test strip volume per month?	See response to Question 14.
23	Regarding Section 4.2 Bid and Product or Service Requirements – Does the Department have a ratio of fentanyl test strips per unit of naloxone that can be used to help estimate fentanyl test strip distribution quantities?	No, See response to Question 14.
24	Regarding Section 4.3 Estimated Quantities and Delivery Requirements – What is the smallest quantity of naloxone shipped in your program? (i.e., Do programs order by the case? Or do programs order by the unit (two-dose carton)?) Is there a maximum case size? Not all manufacturers have the same case size. Will 24 two-dose cartons be an acceptable case size, or will the Department require 12 two-dose cartons per case?	The minimum units for naloxone and fentanyl test strips will be negotiated with the awarded contractor.
25	Regarding Section 4.5, please provide clarification on, "Contractor must provide a delivery option to shipping centers if an agency delivery point of contract is not available." Are you asking for the option to deliver to a standalone shipping store (i.e an independently owned location such as "The UPS Store")? Please provide clarification.	If an agency doesn't have the ability to have delivery to their location the selected vendor must have the ability to ship to a shipping center like a UPS store or CVS pharmacy location.
26	The Contractor will be required to follow the direction of the Department or designee, as well as the security personnel teams to ensure that the Contractor is always compliant with all facility-specified security policies." The security requirements are vague.	The awarded contractor will be held to all security information as detailed in Attachment 8 and other contractual documents. As stated in Section 4.6, the awarded contractor will work with the Department or designee to obtain necessary clearances.

	Can you please provide clarity on the security policies that the Contractor must follow? When will suppliers have access to detailed security policies that must be followed?	
27	Regarding Attachment 8 DOH Agreement (Standard Contract) – The New York State Health Department Appendix, Section I. General Terms and Conditions, Subsection M. and Section III. Term and Termination, Subsection H.1. refer to audit and inspection rights of the Department. Could the Department please clarify the intended scope and purpose of these provisions, including the types of audits and inspections that the Department would like to conduct and anticipated duration? Would the Department be open to working with Contractor to define and agree upon a scope for audits and inspections in advance and to provide reasonable advance notice for an audit or inspection? Additionally, would the Department consider granting Contractor the right to audit the Department to ensure the Product that is the subject of this Bid is used as set forth in these terms and conditions that will be agreed to by Contractor and the Department and that Certifications required by Contractor are being maintained by the Department?	Reasonable advance notice of any inspection, audit, or examination that the Department may wish to undertake pursuant to the cited provisions of the New York State Department of Health Appendix, the Department would be willing to consider any proposal Contractor under the awarded Contract pursuant to the IFB may wish to discuss, but is pessimistic about the likelihood to provide greater definition than those provisions currently provide because: (A) the Department, or another agency of the State (for example, the Office of the State Comptroller, the Office of the New York State Attorney General, The Division of Taxation and Finance, or the Department of Labor), is unlikely to exercise any inspection or audit right if the Contractor is fully performing its obligations under the terms of the Contract, and (B) if an inspection or audit is conducted upon the termination of the Contract, the possibilities one can imagine range from a pro forma inspection of Contract records to a full forensic audit of books and records and staff interviews. Prior advance notice for any audit or inspection will almost certainly be required.

28	Regarding Attachment 8 DOH Agreement (Standard Contract) – The New York State Health Department Appendix, Section III. Term and Termination, Subsection C. provides that the Department may terminate the Contract in the event Contractor fails to comply with the terms of the Contract however Section III. Term and Termination, Subsection C. does not provide Contractor the opportunity to cure and notice is only ten days. Would the Department be willing to provide Contractor with reasonable notice and opportunity to cure prior to terminating the contract?	No, the Department would not be willing to provide Contractor with reasonable notice and an opportunity to cure pursuant to Section III.C. of the NYSDOHA.
29	Regarding Attachment 8 DOH Agreement (Standard Contract) – The New York State Health Department Appendix, Section VIII. Subcontracting, Subsection A. requires Contractor to obtain prior written approval of the Department prior to subcontracting services. Contractor would like to better understand the intent of this provision. Specifically, would the Department consider accepting notice of subcontractors engaged to provide services instead of requiring prior approval of such subcontractors? This would help facilitate timely provision of services.	No, the Department will not accept notice of subcontractors engaged to provide services.
30	Please specify what bidders must submit to meet each of the three requirements of §3.1.	The Bidder must submit documentation that provides sufficient evidence of meeting the minimum qualifications to bid. This documentation may be in any format needed to demonstrate how the bidder meets all of the minimum qualifications.

31	With respect to the first bullet of §3.1, please clarify the following: a. Whether the “shipping, distributing, and tracking of a high volume (45,000 per month) of opioid antagonist” has to be pursuant to government contracts? b. Is the term 'requestor' being used in general terms to refer to all registered programs/locations, or is the state specifically seeking documentation of the ability to ship, distribute, and track a high volume of opioid antagonist to a single location?	a. No, shipping, distributing, and tracking of a high volume (45,000 per month) of opioid antagonist does not need to be pursuant to government contracts. b. The term requestor is referencing any contractor that the bidder has shipped naloxone to during the timeline outlined in section 3.1. It does not reference direct contracts with the Department of Health.
32	First paragraph, please clarify how many packages of naloxone and fentanyl test strips constitute an “order”.	The current minimum requirement is 48 units of naloxone per order. The minimum units for naloxone and fentanyl test strips will be negotiated with the awarded contractor. See response to Question 24.
33	Second paragraph, the IFB states that fentanyl test strips “have not been subject to any State or Federal regulatory regime or process.” a. As bidder does not manufacture the fentanyl test strips, would DOH delete the requirement for the bidder to provide “quality control measures”? b. If the fentanyl test strip manufacturer conducts testing and releases each lot of fentanyl test strips prior to distribution, is the bidder still responsible for performing additional testing (i.e., contracting with a lab) on the fentanyl test strips, or can the bidder rely on the quality control measures provided by the fentanyl test strip manufacturer?	a. No, as per Section 4.2 of the IFB, the Contractor must employ quality control measures to validate each lot before distribution to the community b. The testing must be done outside of the manufacturer’s testing. c. The quality control the Department is requiring is for the contractor to test each lot of FTS via a lab to ensure the validity of the strips. Once the validity is confirmed shipping of the lot can occur. d. A “lot” is determined by a company when a product is developed. Every time a product lot number changes a new number is given to the product. Lot numbers change when there is new production of the product. e. If a lot fails, the product cannot be used or shipped. A new lot must be tested and approved.

	c. Please specify the “quality control measures” required by DOH. d. Please specify what constitutes a “lot” of fentanyl test strips. e. Please specify what action DOH requires if a lot fails to meet the quality control measures. f. Please confirm that any potential developments in quality control measures will be addressed by means of a contract amendment.	f. Per Section 4.2. as the testing technology evolves the Department will work with the selected vendor to adapt to new developments.
34	Fifth paragraph, the IFB states orders of naloxone and test strips “must be shipped concurrently” and that orders for test strips “can range anywhere from 0-1,000 per order of naloxone” as determined by the program. Please confirm that the naloxone and test strips can be shipped separately in response to an order from the program.	See response to Question 20.
35	The intended use of the fentanyl test strips provided by the bidder is for individuals to test drugs for the presence of fentanyl; not to test their urine for the presence of fentanyl. IFB Section 2.1, Introductory Background, states that fentanyl test strips “are federally regulated for detecting fentanyl in an individual’s urine and currently have not been subject to any regulatory process outside of drug testing in urine.” Additionally, Section 4.2, Bid & Product or Service Requirements, states that the fentanyl test strips “have not been subject to any State or Federal regulatory regime or process which has	The Department is imposing quality control measures to ensure that each lot of FTS that is developed and shipped by a vendor has been verified and checked for validity. The Department is aware that FTS have false positives and negatives. It has been founded that the issues arise based on the way each lot is developed. The Department is requiring that the contractor contract with a lab to conduct validation testing on each lot prior to shipping. Please reference section 4.2 of the IFB.

	led to variations in accuracy among brands and testing strips when testing drug samples." However, IFB Section 4.2 requires the bidder to provide "quality control measures" for the testing of the fentanyl test strips but does not specify what those measures are. Please clarify whether as a result of the quality control measures, DOH and the IFB is requiring that the bidder represent and warrant the fentanyl test strips for the purpose of testing drug samples.	
36	Please clarify whether integration of any vendor or shipping systems with the DOH system is required.	No integration of vendor or shipping systems is required.
37	Please clarify whether this requirement requires a single designated staff member or whether multiple staff members (i.e., both contractor and subcontractor) can be responsible for managing logistics as well as data entry into the web-based portal, or do those duties need to be separate and given individually to different staff members?	The dedicated staff person is one single designated staff person.
38	Please clarify the required availability of the "dedicated person on staff" (i.e., M-F and 9-5 EST).	The dedicated staff person is expected to be available during standard business hours, M-F from 9am – 5pm EST.
39	Please list the "department holidays".	Department holidays are determined by the New York State Department of Civil Service every year, and details are published to their website annually. Please follow the link for a list of Department Holidays. https://www.cs.ny.gov/attendance_leave/2025_legal_holidays.cfm
40	Please provide additional information on what the following tasks entail: invoicing, vouchering,	The contractor must provide bi-weekly invoicing and vouchering detailing product that the Department is expected to pay. The

	billing reconciliation, and associated invoice numbers to registered programs certificate numbers?	contractor is expected to submit excel files matching the format of the Department's reconciliation file bi-weekly. These excel files must have correlating invoice numbers and program certification numbers.
41	Please clarify whether DOH requires signature confirmation or proof of delivery for all shipments of naloxone and/or fentanyl test strips.	All shipments require proof of delivery. Proof of delivery can be completed via a signature or obtained by program staff directly via the ordering system.
42	Please provide clarification for the billing process as Section 4.7 reads- "Contractor must bill the Department biweekly (example 01/01/2025 – 01/15/2025 & 01/16/2025 – 01/31/2025) for the shipment of products, this includes fentanyl testing strips and naloxone"; and the NYS Department of Health Appendix, Section II- B (last paragraph) reads- "Payment terms shall be: The Contractor will submit monthly invoices, due 30 days after the end of each month, which must be accompanied by a New York State Claim for Payment (form AC3253S) to ensure payment."	The awarded contract will include biweekly invoicing as stated in Section 4.7 of the IFB. The New York State Department of Health Appendix Section II B will be updated at time of contract award to reflect biweekly invoicing requirements.
43	Please clarify whether bidder must provide subcontractor agreements with the bid.	Subcontractor agreements do not need to be submitted with the bid.
44	The IFB is not clear on what bidder must submit in order to have a responsive bid. Section 4, Detailed Specifications, requires Bidder to "provide responses that addresses all of the requirements of this IFB as part of the Bid." However, the following IFB sections do not list Section 4 in what the Bidder must submit to have a responsive bid: Section 6.1.2, Bidder's Minimum Qualifications to Bid; Attachment A, Bid Package Checklist; and Attachment B, Bid Form.	Bidders are instructed to follow Attachment A - Bid Package Checklist in order to be responsive to this IFB.

	Attachment B, provides that the bid form complies with the "format and content requirements" in the IFB and Attachment B; and failure to do so "will result in disqualification." Please clarify what Bidders are required to submit for a responsive bid, including, what, if anything, Bidder must submit to demonstrate compliance with each requirement in Section 4, including, but not limited to, §§'s 4.2, 4.3, 4.4, 4.5, and 4.8.	
45	When referencing shelf-life, is the state focused on the date of manufacturing or date of shipping?	The manufacturing date is what the Department is referencing, not shipping date.
46	Please confirm that the reference to "total bid price" in the method of award in §8, Method of Award, is to the "total bid price" column in each of the tables in Attachment B, Bid Form, which is for naloxone alone, and does not include the fentanyl test strip price per strip in Attachment B, Bid Form. If not, please clarify.	The total bid price is the sum of the "total bid price" column in Attachment B plus the all-inclusive price per strip.
47	If a certified M/WBE subcontractor for fentanyl test strips is unavailable, what documentation would demonstrate an adequate "good faith effort" to justify a waiver?	The contractor would save documentation that reflects their research, outreach, and any/all attempts to identify NYS-certified MWBE subcontractors.
48	Upon being awarded the bid - what is the notification date that you have won the award, and will there be a period to ramp-up production before 1st orders are placed?	The bidder will receive written notice of intent to award approximately three (3) months prior to the projected start date of the contract, which is 12/1/25. There will not be a ramp-up for production prior, orders are expected to ship one week after execution of contract. Please see Amendment #1.

49	The bid specifies 4mg product – How and where should we specify in the bid that RiVive is a 3mg solution?	As stated in the IFB, 4mg is the naloxone variation that the Department is currently soliciting for a bid. The 3mg variation is not an approved variation on the Commissioner of Health's standing order.
50	Please provide clarification on how both the naloxone and test strips need to be shipped. Can they be in separate boxes within the same shipment?	See response to Question 20.
51	Can a separate invoice be generated for the fentanyl testing strips or does it have to be combined with the naloxone product?	Separate invoicing is preferred.
52	Is the Department open to or interested in a private-labeled naloxone product under a New York State-specific label?	The Department is open to all bidders that meet the minimum qualifications outlined in the IFB.
53	On page 4, Section 3.1 of the IFB states: "The Bidder must have a minimum of two (2) years of experience manufacturing, direct shipping, distributing, and tracking a high volume (est. 45,000 per month) of opioid antagonist of the naloxone classification shipments to the requestor." Could the Department please clarify whether: 1. The "requestor" refers specifically to the NYS Department of Health (i.e., experience must be with NYS), or 2. If equivalent experience with other public agencies or overdose prevention programs (in other states or jurisdictions) will satisfy this requirement?	See responses to Questions 6 and 9.
54	Section 3.1: If experience outside of New York State is acceptable, what specific information or documentation should bidders submit to provide	Section 6.1.2 states that the Bidder must submit documentation that provides sufficient evidence of meeting the minimum qualifications to bid. This documentation may be in any format

	sufficient confidence in their ability to meet the state's requirements?	needed to demonstrate how they meet those minimum qualifications.
55	Attachment B: The bid form includes options for naloxone products with varying shelf-lives (2 to 4 years). Does the Department have a preference or incentive weighting toward longer shelf-life products in the evaluation process?	No, the Department does not have a preference or incentive weighting toward long shelf-life products.
56	Attachment B: If Naloxone Expiry is expected to increase can the bidder list in out years different dates per the schedule?	The tables in Attachment B must not be modified or altered in any way.
57	Attachment B: What is the expected shelf life upon receipt of naloxone, and should the table be filled out using "shelf life at receipt" or "FDA approved shelf life"? Also, if the manufacturer expects extended shelf life for 2026 and beyond, can we fill out multiple tables for each year?	There is no shelf-life minimum qualification included in the IFB. You must only fill out one table for what is currently approved by the FDA. As stated in Attachment B, Bidders must complete ***only one bid table for naloxone product.*** Bidders must complete the bid table which corresponds to the shelf-life of the product that they can provide.
58	Section 4.3 - 4.4: The IFB mentions that the contractor must input data into DOH's existing naloxone ordering and tracking portal. Will training, access credentials, or technical support be provided to ensure smooth onboarding into this system?	Yes, the Department will work the selected contractor to ensure that access and training occur.
59	Section 4.5: Will access to OOPP addresses be permitted prior to contract execution?	Attachment C for this IFB is a provider directory that lists most of the zip codes for registered programs, some are private and not public facing. The selected bidder and Department will address any remaining contacts needed upon selection.
60	Section 8: How will the bids be scored and what carries the most weight in the scoring?	As stated in Section 8. Method of Award, the Department will award one contract as described in this IFB to the responsible and responsive Bidder who offers the lowest total bid price and meets all minimum qualifications.

61	Section 4.3: Does NY anticipate consistent monthly volumes (e.g., 35,000-45,000 units), or will there be seasonal or surge ordering patterns that the contractor should be aware of and plan for?	The Department has months where monthly volumes are higher and lower than the averages that were included in the IFB. Events and community spikes vary and ordering increases when these two things occur.
62	Section 4.2-4.3: Is there an estimated volume of Fentanyl Test Strips annual for this contract?	See response to Question 14.
63	Section 4: Does NY DOH require just one test strip manufacturer, or would a combination of test strip manufacturers be acceptable for this bid? Is there flexibility to switch between test strip manufacturers in the event of a supply chain disruption or in an effort to optimize our offering in the future?	The Department expects one manufacturer to be contracted with for supplying FTS. Changing test strip manufacturers is permitted and new contracts would need to be put in place.
64	Section 4 and 4.8: Are there any specific data reporting requirements related to the distribution and use of the fentanyl test strips that the Contractor and their subcontractor will be responsible for? Can you provide an example of the type of data collection DOH is requesting as part of the staffing requirements?	At this time the Department is only asking that shipping information (address, number of strips) be collected and entered into the Department's Opioid Overdose Prevention System.
65	Section 4 and Attachment B, page 2: Is there a required configuration (e.g., packaging, number of strips and instructions) for the fentanyl test strips being requested?	There is no configuration that is developed currently. The expectation is that the vendor will ship the strips as they are ordered.
66	Attachment B, page 2: The Contractor must employ quality control measures to validate that each lot before distribution to the community and contract with a lab for validation. – could you	FTS validation is being required as outlined in the IFB Section 4.2. Each individual lot of FTS are developed individually and thus need verifications from a lab on their validity. Each time there is a lot change new validation testing must occur. A

	explain with more detail? Will a certificate of validation from the manufacturer suffice or will the winning vendor need an independent lab to validate the test strip work? What other, if any, specific documentation or evidence is required from bidders and their subcontractors to demonstrate compliance with these requirements for both products?	certificate of validation from the manufacturer will not meet the standards outlined in the IFB, you must use an outside lab for validation.
67	Section 4.8: How will the Department evaluate the experience and qualifications of proposed subcontractors, particularly concerning their experience with manufacturing, quality control, and distribution of fentanyl test strips?	The Department will conduct a vendor responsibility review of proposed subcontracts, which includes a review of the vendor's financial and organizational capacity; legal authority; integrity; and previous contract performance.
67	Section 4.8: What documentation is required from the subcontractor as part of our bid submission to demonstrate their capacity and compliance with the IFB requirements?	There is no documentation required with bid submission for any proposed subcontractors.
68	Section 4.8: What is the process for obtaining the Department's prior written approval for a subcontractor, as required by Section 4.8?	The awarded Contractor must submit a written request for approval of a proposed subcontractor to the point of contact identified by the Department, and, upon request by the Department, provide a copy of the proposed subcontract
69	Section 4.4: How will communication and coordination between the Department, the prime contractor (our company), and the subcontractor be managed regarding orders, shipping, billing, and any potential issues?	The Department will work with primary contractor to discuss any issues or potential problems. It is the responsibility of the contractor to ensure that the FTS subcontractor is meeting the standards of the developed contract.

70	Section 4.7 states that the Contractor must bill the Department biweekly for the shipment of products, including both fentanyl testing strips and naloxone. When partnering with a subcontractor for the fentanyl test strips, is there a preferred method for handling the billing of the test strips portion? Will the prime contractor bill the total amount and then compensate the subcontractor, or is a different arrangement expected?	The awarded contractor will handle the submission of all vouchers, including those for FTS. The payments will be made to the contractor for all products. The awarded contractor is responsible for making payments to the subcontractor. The billing for naloxone and FTS should be made separately on individual POs and sent to the Department bi-weekly.
71	Section 4.4: How will billing reconciliation be handled by the Department when a subcontractor is involved?	The awarded contractor will handle the submission of all vouchers, including those for FTS. The payments will be made to the contractor for all products. The awarded contractor is responsible for making payments to the subcontractor.
72	Section 4.5 and 4.3 outline shipping requirements, including delivery within 3-5 business days of an order being placed through the Department's website order portal, providing tracking numbers, and maintaining tracking information in the portal. When working with a subcontractor for fentanyl test strips, is it required that both the naloxone and fentanyl test strips be shipped together as a single shipment from the prime contractor, or can they be shipped separately by the prime contractor and subcontractor, with coordinated delivery? If separate shipments are permissible, how should the tracking information for both shipments be entered into and managed within the Department's ordering system to ensure programs receive complete orders and the Department has full visibility?	Shipping of the products can be done separately. The Department's system has the capability for the shipping information for fentanyl test strips and naloxone to be entered separately. The selected contractor will be responsible to enter all shipping information for both products. A training for the selected contractor will occur once contract is executed.

73	Section 4.5 mentions providing a delivery option to shipping centers if an agency delivery point of contact is not available. How would this apply if a subcontractor is handling the shipping of the fentanyl test strips? Also, is this applicable for naloxone?	This is applicable for both naloxone and FTS. The programs will select the shipping option in the ordering system. A shipping center is sometimes selected when a location cannot/will not be available.
74	Section 4.2: Is there a preferred brand for fentanyl test strips?	No, there is no preferred brand for fentanyl test strip.
75	General: Do fentanyl test strip instructions/naloxone instructions need to be in multiple languages?	No, the Department will be handling the fentanyl test strip instruction information.
76	General: Are there any expectations or requirements for the awarded contractor to provide training or educational materials regarding the use of naloxone or fentanyl test strips?	No, the Department has internal resources for these two products.