Guidance and Tips for Submitting a Full Review Establishment with Construction CON for a Midwifery Birth Center

INTRODUCTION

This guidance document is provided to help clarify the application process to establish and construct a new Midwifery Birth Center, and to compile relevant information in one source. This guide contains important instructions and information to assist in the preparation of such application.

Each Certificate of Need Application is reviewed for public need, financial feasibility, architectural and engineering standards, character and competence, and legal issues related to the organizational structure of the proposed operators and/or contractual arrangements. The certificate of need application requests information necessary to complete thorough reviews in each of these areas.

To obtain approval to operate a Midwifery Birth Center in New York State, applicants must submit a Full Review Establishment with Construction Certificate of Need (CON) application through the New York State Electronic Certificate of Need (NYSE-CON) system for review and approval.

For CON purposes, *Establishment* means Public Health and Health Planning Council approval of an Article 28 health care provider to operate in NYS and *Construction* means approval by the Department of Health (DOH or the Department) of the health care services to be provided at the site and under the physical conditions proposed by the applicant.

HELPFUL LINKS

General CON information, including an overview of the process and links to schedules and forms, can be found here: <u>Certificate of Need for Article 28, 36, 40</u>

Most Establishment CONs must be submitted through the Public Authenticated NYSE-CON system. Training Documents for submitting CONs through the NYSE-CON system, including creating an account for access to create a submission, can be found here: <u>Public Authenticated NYSE-CON</u> <u>Training Documents</u>. Once in NYSE-CON, when creating the new submission, the following "path" must be followed:

New Facility/Agency → Midwifery Birth Center → New Facility or Agency with Construction

MAJOR STEPS in the CON/LICENSURE PROCESS

Step 1 - Application

• Submission of the CON through NYSE-CON

Step 2 - Review

• DOH staff review the CON and work with the applicant to gather any additional information needed to process the application

Step 3 – Public Health and Health Planning Council (PHHPC)

- DOH presents its recommendation to the Establishment and Project Review Committee of PHHPC for review and recommendation to the full PHHPC
- The CON is presented to the full PHHPC for a determination
- Step 4 Approvals
 - Upon PHHPC approval, the applicant responds to any Contingencies of Approval, as applicable. Contingencies are often items not present or ready at the time of application but are required for final approval (e.g., design development drawings).
 - Receive Final PHHPC approval of the Operator entity and DOH approval to start construction, as applicable
 - Contact the DOH Regional Office to commence the pre-opening process
 - File legal documents with the Department of State, as applicable.
 - Attend pre-opening survey and address any deficiencies, as applicable
 - Receive final DOH approval to operate and the facility's operating certificate

CON APPLICATION TIPS

- ✓ Complete CON applications that contain thorough responses are easier to analyze and allow for a faster review. When applications are incomplete, the Department requests the missing information in the form of correspondence through NYSE-CON to the applicant which can lengthen the review process.
- All required Tabs (found within the NYSE-CON application) and Schedules must be included in the application submission. However, not all parts of all schedules may be required. Follow the instructions in each schedule to determine which sections are relevant to your CON.
- ✓ Ensure that information in each schedule is consistent with the information provided in all other schedules.
- ✓ The information included on the next few pages includes common omissions, defects, and confusion points, but it is not intended to include every required element of an application.
- ✓ Contact <u>cons@health.ny.gov</u> with any questions you may have.

TABS and SCHEDULES)

At the time of this writing, the following Schedules and NYSE-CON Tabs are required for Full Review Establishment with Construction CONs for Midwifery Birth Centers. All "Tabs" are filled in online in the application as it is being created. All "Schedules" are uploaded into the Application Tab of the application being created, and all attachments to the schedules are uploaded there as well.

General Tab **Executive Summary Tab** Sites Tab Schedule 1 Schedule 2 Schedule 3 Schedule 5 Schedule 6 Schedule 7 Schedule 8 Schedule 9 Schedule 10 Schedule 11 Schedule 13 Schedule 14 Schedule 24

GENERAL Tab

This tab provides some basic information about the application. This is where the viewer can find information on the proposed operator entity, the contact information, and the alternate contact information. Please ensure a principal of the proposed operator is the primary or alternate contact.

EXECUTIVE SUMMARY Tab

This is a narrative summary or overview of the project. This should include the purpose of the project, information about the proposed operator, the service(s) the facility is adding, and any other information that gives the Department and the public a base understanding of the application request.

SITES Tab

This tab will include the name and address of the proposed site(s), as well as the services to be provided at the site(s). Please see the NYSE-CON Training document for how to add the new location and choose the services: <u>Public Authenticated Sites Tab Training Document</u>

SCHEDULE 1 General Information

Complete as Instructed. The primary and alternate contacts should be the same as what is listed in the General Tab.

SCHEDULE 2 Personal Information

- **Schedule 2 Tracker:** Either upload the provided tracker or a spreadsheet with the same columns. This serves as a checklist for both the applicant and the reviewers ensuring all required components of Schedule 2 have been provided.
- **Schedule 2A**: A separate Schedule 2A must be filled out by each individual with an ownership or financial interest in the organization, as well as the officers, directors, members, and/or managers (dependent on the legal entity type). *Every question must be answered, indicating "None" or "N/A" if appropriate*.

The following specific items are frequently incomplete and delay the reviews:

- Section 3 Professional Licenses Held: You must provide all licenses, in every state, including license numbers and expiration dates.
- Section 4 Employment History for Previous 10 years: You must provide the *full 10 years* of employment history, addressing any gaps. When describing your employment, please fully *describe* your position (not just listing your title) and describe how this contributes to the competency of running a healthcare facility. If you are submitting a CV or resume, please ensure that all requested information on the Schedule has been included in your CV/resume.
- Section 5 Office's/Ownership Interests:
 - Affiliated facility/agency disclosure must include *all* health care entity ownership (regardless of the size of the interest), as well as memberships on not-for-profit boards, during the past ten years, even if the affiliation has ceased. You must provide the *dates (including month and year)* that the office or ownership interest was held. Also please provide the name and address of the licensing agency.
 - If the facility has an enforcement action against it, please describe the enforcement action and whether the action has been resolved.
 - Applicants with no or limited experience in providing health care services are evaluated based on, among other factors, compliance with laws and regulations pertinent to their business or profession, the status of any professional licenses, and any relevant community and/or volunteer background and experience. *Every* applicant must complete an affirmative statement explaining their qualifications to operate the proposed facility.
- Section 6 Record of Legal Actions: Answer *all* questions. In the case of a "yes" response, provide a description including the date, the location, the type, and the status of the action.

- The Schedule 2A must be signed, dated, and notarized or it will not be accepted. It must also be dated less than six months before the CON is submitted.
- Applicants with no or limited experience in providing health care services must ensure that a Schedule 2A is submitted for the proposed Center Director.
- Schedule 2B: A separate Schedule 2B must be filled out by each individual unless they are Directors of not-for-profit corporations who will not contribute capital to the project (see Schedule 2C). A proposed Center Director who is required to submit a Schedule 2A because the applicant has no or limited experience should *not* submit a 2B, unless they are part of the applicant entity. All 2Bs must be signed and notarized.

The most relevant items to be shown on the balance sheet are as follows:

- Assets Cash, Stocks and Bonds, Cash surrender value of Life Insurance (Liquid Assets)
- Liabilities Mortgages payable which shows any major debt.

For MBCs-only, As an alternative to submitting a 2B, the Department will allow MBC applicants that have an *executed* loan commitment to fund project costs and/or working capital start-up needs to submit the executed loan commitment and the Business Plan they provided to their lending institution to secure the business loan(s) in-lieu-of the individual Schedule 2Bs.

- **Schedule 2C:** A separate Schedule 2C must be filled out by each Director of not-for-profit corporations who will not contribute capital to the project. All 2Cs must be signed and notarized.
- **Schedule 2D:** Compliance reports for affiliated out-of-state health care entities are required at the time of submission of the CON. See the schedule instructions and guidance for obtaining compliance reports.

SCHEDULE 3 Legal Information

Complete as instructed for the legal entity type. Ensure that all submitted legal documents, including proposed legal documents, are executed.

SCHEDULE 5 Working Capital Information

Working capital is the term used to describe the funds needed to initiate operations of an entity and meet initial cash flow needs until revenues can support operations.

Section 1: Provide a monthly-cash flow analysis for the first three years of operation. Provide details regarding all sources of working capital funds (e.g., cash, grants, donations, loan). Borrowed funds are limited to 50% of total working capital requirements (typically estimated based on two months of the third-year budgeted expenses for new start-up operations). If borrowed funds are a source of working capital, please summarize the terms and attach a letter of interest from the intended lender, to include an estimate of the principal, term, interest rate and payout period being considered.

For MBCs-only, the Department will refer to the applicant's Schedule 2Bs **or** the Business Plan and Ioan commitment(s) submitted in-lieu-of the Schedule 2Bs to verify the availability of resources for start-up.

Section 2: Provide a Pro Forma Balance Sheet to show the financial status as of the first day of operations. The purpose of the Pro Forma Balance Sheet is to show that there is cash available to operate as an ongoing concern without incurring debt to create negative cash flow.

For MBCs-only, if an executed loan commitment and business plan are submitted in-lieu-of the Schedule 2Bs, the Department will attempt to use the information contained therein to assess the applicant's ability to meet initial cash flow needs as projected in the submitted cash flow analysis.

SCHEDULE 6 Architectural Information for Birth Centers

This Schedule should be completed in its entirety by the project architect's firm. MBCs are reviewed under NYCRR Title 10, Chapter V, Article 2, Part 711.

- NFPA 101, Life Safety Code, 2012 Edition, Chapter 38 for Business Occupancy
- FGI 2014 or 2018 Edition, Specific Requirements for Birth Centers

Additionally, dependent on the size of the MBC, the Department is affording flexibility in the standards as indicated on the Birth Center Classification Matrix found on the Department website.

Instructions for completing Schedule 6 are found on page 1 of the schedule. Components to be submitted for review include:

- Architect/Engineer Letter of Certification: To be completed by a NYS licensed architect or engineer confirming project compliance to applicable regulations.
- Architectural Narrative: Written, detailed project description to convey building information, facility space, associated building systems, and fire protection. Answer all project description questions on pages 2 and 3.
 - List the project scope; e.g., "This project will consist of new construction and/or renovation consisting of a total of 5,000 SF to include a lobby, waiting room, reception area, 6 exam rooms, 2 administrative offices, soiled workroom, nurse station, and 4 birthing rooms."
 - For renovation projects: describe the existing use of areas to be renovated and where those functions will be relocated. Note which functions and spaces are being removed or added.
- **Schematic Drawings**: Schematic drawing submission is the primary review to ensure project scope, NFPA, and FGI compliance. See page 4 for the list of drawings to be submitted. When reviewed and deemed acceptable, this level of review is given "Contingent Approval."
 - Floor plans: 1/8" minimum scale. Identify 2 means of egress to NFPA compliant exits (include ground floor plan if necessary, confirming exit discharge), path of travel for patients, visitors and staff, and location of fire and/or smoke partitions.
 - Site plan: Existing floor plans may be used where applicable to show minor construction. The accuracy of existing plans must be verified by an architect or engineer.
- **Design Development/State Hospital Code (SHC) Drawings**: Design Development drawing submission is the secondary review and is to ensure State Hospital Code compliance. These drawings are typically submitted after the applicant has received a "Contingent Approval Letter." See page 4 for the list of drawings to be submitted. When reviewed and deemed acceptable, this level of review will satisfy the architectural contingency ("Contingency Satisfaction").
 - Floor plans: 1/8" minimum scale. Detailed and complete with all spaces, circulation, and building systems designed.
 - Vertical circulation for high-rise buildings: identify egress stairways and elevator access.
 - Mechanical, Electrical, Plumbing and Fire Protection: identify compliance on floor plans and reflected ceiling plans.
- **Combined Drawing Review**: For projects of minor construction and scope, an applicant may request a single-step review by initially submitting Design Development drawings and noting such request within the Architecture/Engineering Narrative. See page 4, Required Attachment Table, for the list of drawings to be submitted for "Contingency Satisfaction". Compliance with all requirements must be shown.
- Limited Birth Center Drawing Review: For projects that meet the parameters of a Limited Birth Center under the Birth Center Classifications matrix, an applicant may submit a shortened Design Development drawing set for a single-step review, eliminating the need for the architectural contingency for State Hospital Code compliance review. See page 4, Required Attachment Table for Limited Birth Centers, for the list of drawings to be submitted for "Single-Step Review".

SCHEDULE 7 SEQR Information

Complete as instructed.

SCHEDULE 8 Project Cost Information

Pay attention to the Source location for each cell in the spreadsheet, if applicable. Entries/values should match across schedules. The anticipated construction dates should consider the CON process, including PHHPC and contingency satisfaction, as applicable. Follow the Schedule based on the costs estimated by your architect and sub-total the cost amounts. Additional information will need to be added if financing costs are relevant in obtaining the funds to construct. New Construction is construction that occurs in a new building or new wing including the related equipment. Renovation is construction that occurs within the confines of an existing enclosure including the related equipment.

Schedule 8B: Generally, detailed estimates and itemized lists supporting specific line items are **not** required to be submitted with Schedule 8B. However, reviewers may follow up with applicants to provide more details for specific lines if the information appears to be outside of what is typically seen for the particular line item.

- **Column A:** This is the cost as if construction was to start on the date the application is submitted.
- **Column B:** Enter the increase in cost that you estimate will occur by the midpoint of the construction period in column (B) and enter in the heading of column (B) the percentage that you use to calculate this figure. If the construction period is less than one year it is not necessary to complete column (B).
- **Column C:** This column should be used to determine the final Total Project Cost and associated processing fees. To estimate the processing fee correctly, multiply the processing fee percentage by Line 8. The form includes a link to the website where the fee percentages are listed. The CON approval letter will include the DOH-determined fee assessment.
- Site Development (Line 2.3): Examples include but are not limited to: site clearing, demolition, grading, excavating, water, sewer, storm drainage, concrete curbs and sidewalks, asphalt paving, retaining walls, brick pavers, hydro-seeding, erosion control.
- **Temporary Utilities (Line 2.4)**: Examples include temporary electricity, heat, and water.
- **Design Contingency (Line 3.1)**: No more than 10% of lines 2.1 and 2.2 will be allowed. The design contingency is to be used only to refine the design between the time the CON is submitted, and when the construction has begun.
- **Construction Contingency (Line 3.2):** No more than 5% of line 2.1 (for new work) and 10% of line 2.2 (for renovation and demolition) will be allowed.
- Fixed equipment (NIC) (Line 4.1): Provide a detailed list of fixed equipment not included in the construction lines (2.1 and 2.2). Fixed equipment is generally defined as large equipment that requires attachment or installation to the building structure, and often an integral part of a building. For a more detailed explanation, see the <u>Estimated Useful Lives of Depreciable</u> <u>Hospital Assets Revised 2018 Edition</u> American Hospital Association Chicago Pages ix and x
- Movable Equipment (Line 5.1) (from Schedule 11 total amount): A detailed Schedule 11 must be included. Moveable equipment is generally defined as equipment capable of being easily moved from one site to another. For a more detailed explanation of Major Movable Equipment and Minor Movable Equipment, see the <u>Estimated Useful Lives of Depreciable</u> <u>Hospital Assets Revised 2018 Edition</u> American Hospital Association Chicago Pages ix and x

SCHEDULE 9 Project Financing Information

Provide information on how you will finance the total project cost you have estimated on Schedule 8B. Total project financing should equal the total from Schedule 8B line 10 in almost all cases. The 8B and 9 figures may not match in certain types of applications, such as projects refinancing existing debt. A 10% equity requirement is needed for all construction projects. This would be derived from the proposed members' liquid assets (not net worth). This could be reduced to 5% if the applicant can provide a cost savings to Medicaid in their business plan equal to or better than the 5% equity. The remaining 90% (or 95%) can be financed from a bank mortgage or loan.

SCHEDULE 10 Space & Construction Cost Distribution

A detailed Schedule 10, broken down by building, floor, and functional code, is required for all projects involving construction. Functional Codes can be found by selecting the Schedule 10 Lookups tab at the bottom of Schedule 10. New construction and renovation must be entered on separate schedules.

- **Total Construction Costs (Column H):** These are costs at the time the application is filed. These costs must be carried over to Schedule 8B Column (A): either on line 2.1 "New Construction" or line 2.2 "Renovation and Demolition."
- Space Description (Columns A through F):
 - Enter the building number in **Column (A)** and the floor number in **Column (B)**.
 - Use the *Functional Code Lookup tab* (Appendix A) to complete **Column (D)**. Any functional codes not listed in the appendix should be entered as code 900 OTHER in column (D).
 - Column (E) should populate automatically based on the code selected from Appendix A.
 - Enter an asterisk (*) in Column (F), when reporting building systems work which is necessitated by work in a functional area and located outside this functional area. List the building systems work on the next line directly following the program area which requires the building systems work.
- **Cost Estimate (Column G):** The cost estimate should be in first quarter dollars of the year the application is submitted. Columns (F) and (G) should be subtotaled for each building. A sum of the subtotals should be shown at the end of the report in the row entitled "Totals for Whole Project."
- Total Construction Cost (Column H): Column (H) equals Column (F) times Column (G).
- Alterations, Scope of Work (Column I): This is for alteration/renovation construction projects only. For each functional category listed, enter one of the following types of alterations:
 - (A) Minor Alterations Use of existing partitions, minor mechanical work.
 - (B) Medium Alterations Some new partitions, half new mechanical work.
 - (C) Major Alterations Gutting and rebuilding.
- **Signature:** This schedule may be completed and signed by the applicant, a representative of the applicant, or by the applicant's architect, engineer, or estimator.

SCHEDULE 11 Moveable Equipment

Moveable equipment is generally defined as equipment capable of being easily moved from one site to another. For a more detailed explanation of Major Movable Equipment and Minor Movable Equipment, see the *Estimated Useful Lives of Depreciable Hospital Assets – Revised 2018 Edition – American Hospital Association – Chicago – Pages ix and x.* Schedule 11 should include a breakdown of each type of equipment, their quantities, and their associated unit cost. If any of the information is outside what is typically seen, the Department will require vendor proposals.

- The functional codes are listed in Schedule 10 in the Lookup Tab (Appendix A).
- Enter either the total lease cost of equipment if the equipment is leased, or the purchase price if the equipment is purchased. If the lease amount is entered, put an "L" in the applicable column. If the purchase price is entered, put a "P" in the applicable column.

SCHEDULE 13 Assurances, Transfer Agreements, Staffing, Revenues and Expenses

- For Staffing, take into consideration the center's proposed hours of operation and projected visits. Describe how you arrived at the staffing numbers and mix. For new Birth Centers, there is no Current Year required.
- If the transfer hospital is more than 15 miles away, and there is a closer hospital, provide a written explanation, as part of the Program Information in Schedule 24, as to why a closer facility was not chosen.
- Applicants with no or limited experience in providing health care services must ensure that a Schedule 2A is submitted for the proposed Center Director.

SCHEDULE 14 Additional Legal Information for Article 28 Entities

Complete as instructed for the legal entity type. Ensure that all submitted legal documents, including proposed legal documents, are executed.

SCHEDULE 24 MBC Program and Need Information

Schedule 24 seeks program information, a summary of public need for midwifery services, and a quantitative projection of utilization. Most of the information regarding the project is presented in narrative form.

- **Public Need:** is reviewed based upon factors and methodologies in regulation. The factors include, but are not limited to, population demographics, service utilization patterns, epidemiology of diseases and conditions, and access to services.
- **Program Information:** Applicants should review the state regulations before creating their programmatic narrative. Additionally, if the transfer hospital is more than 15 miles away, and there is a closer hospital, you must provide a written explanation as to why a closer facility was not chosen.