Annual Report to the Joint Commission on Health Care On the Impact and Effectiveness of the Pilot Programs to Expand Access to Obstetric, Prenatal, and Pediatric Services

Virginia Department of Health

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EXECUTIVE SUMMARY

Over the past several years, many rural, underserved areas throughout the Commonwealth have experienced challenges brought about by the lack of obstetric (OB) providers and the closings of hospital OB units. In response to this health care crisis, in 2004, Governor Warner formed a Workgroup to develop and make recommendations to improve access to prenatal, obstetric, and pediatric care thus helping to ensure healthy babies. This Workgroup, chaired by the Secretary of Health and Human Resources presented a series of recommendations in six key policy areas; reimbursement, insurance, evidence-based practice and licensure, birth injury and access to care. Measures to expand access to prenatal care using a new practice paradigm were suggested. Subsequently, the 2005 General Assembly passed HB 2656 authorizing the State Board of Health to approve pilot projects to improve access to OB care.

Work began in August 2005 when a group of OB Pilot stakeholders and representatives from the Virginia Department of Health (VDH) met to discuss developing one or more pilot sites capable of providing high quality pregnancy related care. Stakeholders determined that two areas emerged as having the greatest need. Low income women and their families from the Northern Neck and Emporia-Greensville areas were negatively impacted by the lack of readily accessible obstetrical care, requiring greater distances to travel to obtain care, thus contributing to the increasing probability of poor birth outcomes.

The stakeholder group continued to meet numerous times over the past 12 months to develop strategies to establish a birthing center utilizing the services of certified nurse midwives (CNMs). In April 2006, the stakeholders presented their business proposal to the Board of Health. The Board reviewed the proposal and requested the stakeholders respond to six items required either in HB 2656 or that the Board considered integral to patient safety.

During this same time the legislature continued to provide essential support needed to improve access to OB care. The *Code of Virginia* was amended to allow CNMs to practice with physician collaboration thus eliminating the requirement for physician supervision of CNMs. In addition, the General Assembly appropriated \$150,000 in 2006 to support start-up costs of the pilots.

VDH has drafted a Memorandum of Agreement (MOA) with Virginia Commonwealth University (VCU) to administer these funds and provide managerial oversight of the pilot projects. The Department agreed that it would be best to hire contractors within each community to serve as project coordinators to continue the work of building community partnerships and developing the birthing center plan. A workplan identifying the tasks and subtasks that are required of each project coordinator based upon predetermined goals within a given timeframe will be used to assess progress over the next year. Each project coordinator is expected to establish programs and develop services leading to a fully operational birthing center in their respective areas by 2008.

VDH will serve as a primary contact for the purposes of collaborating on the implementation of project tasks and priorities and will provide technical assistance for the purpose of expediting the project. VDH will continue to monitor the progress of the pilot projects, and report on the impact and effectiveness of the pilot projects in meeting the program goals.

Background

Small community hospitals, primarily in rural areas of Virginia, have found it increasingly difficult to continue to offer obstetrical (OB) services. This is especially true for hospitals delivering less than 300 babies a year. Figure I (page 12) shows the location of Virginia hospitals that have suspended or closed their OB units as of 2004.

The earlier prenatal care (PNC) begins the better; a factor shown to be associated with lower rates of infant mortality (Kotelchuck, 1994). As shown in Table I (page 7) the number of low birth weight (LBW) babies born in 2004 from the Northern Neck area has increased in six localities over the number of LBW babies born in these same localities in 2003. This may be attributed in part to the number of women who reported receiving inadequate prenatal care in these counties during this time period. In the Emporia-Greensville areas, the percentage of women initiating prenatal care and adequacy of received services (once PNC has begun) was one to three times worse than Virginia's average of 9.4 during 2004. The percentage of low birth weight babies to the total births was greater in seven of the nine counties in the Emporia-Greensville areas than for the State during the same timeframe. Women residing in these areas are faced with the lack of local access to prenatal and delivery services. Lack of access has been shown to be directly related to an increase in the likelihood of premature births which can affect growth and development and lead to challenges in terms of readiness to learn upon school entry.

Based upon the limited availability of obstetric and pediatric care in certain rural areas of the Commonwealth, Governor Warner issued Executive Directive 2 on March 13, 2004 establishing the Governor's Working Group on Rural OB Care. Refer to Appendix A for a copy of the Executive Directive.

Table I VIRGINIA DEPARTMENT OF HEALTH COMMUNITY HEALTH SERVICES VITAL EVENT DATA TABLE 2003/2004 SELECT LOCALITIES

VITAL EVENT	VIRG	INIA	Card	oline	Westm	norland	King (George	Northun	nberland	Richmon	d County	Lanc	aster	Midd	lesex
	2003	2004	2003	2004	2003	2004	2003	2004	2003	2004	2003	2004	2003	2004	2003	2004
Total Live Births	100,561	103,830	311	318	173	179	275	326	97	109	82	95	105	96	71	82
Low Weight Birth (<2,500 grams)	8,278	8,674	21	38	12	14	21	24	6	8	7	16	17	10	4	4
Low Weight Birth Percent of Total Births	8.2	8.4	6.8	11.9	6.9	7.8	7.6	7.4	6.2	7.3	8.5	16.8	16.2	10.4	5.6	4.9
Percent Premature Births	10.8	11	10.9	14.5	11.6	10.6	10.2	15.0	6.2	8.3	11.0	23.2	18.1	16.7	11.3	6.1
Began Care in First 13 Weeks	85,259	88,054														
Percent Began Care in First 13 Weeks	84.8	84.8														
Percent Inadequacy of Prenatal Care	9.6	9.4	7.1	6.6	11.6	10.6	9.1	7.1	14.4	7.3	12.2	12.6	12.4	13.5	4.2	6.1
Infant Death Rate/1,000 Live Births	7.6	7.4	3.2	15.7	17.3	NA	NA	6.1	20.6	NA	NA	42.1	9.5	20.8	14.1	0

Math	news	King V	Villiam	King &	Queen	Es	sex
2003	2004	2003	2004	2003	2004	2003	2004
71	56	180	184	74	68	111	136
3	7	23	11	7	15	10	10
4.2	12.5	12.8	6.0	9.5	22.1	9.0	7.4
9.9	16.1	20.0	9.2	12.2	19.1	9.9	8.1
9.9	10.7	7.2	4.9	10.8	10.3	7.2	5.2
NA	0	NA	10.9	NA	NA	NA	7.4

VITAL EVENT	VIRG	INIA	Emp	oria	Frankl	in City	Greer	nsville	Isle of	Wight	Lunei	nburg	Southa	mpton	Susse	x
	2003	2004	2003	2004	2003	2004	2003	2004	2003	2004	2003	2004	2003	2004	2003	2004
Total Live Births	100,561	103,830	61	63	145	154	127	124	322	355	140	131	172	172	114	123
Low Weight Birth (<2,500 grams)	8,278	8,674	15	7	14	17	20	11	18	26	10	12	21	17	12	10
Low Weight Birth Percent of Total Births	8.2	8.4	24.6	11.1	9.7	11	15.7	8.9	5.6	7.3	7.1	9.2	12.2	9.9	10.5	8.1
Percent Premature Births	10.8	11	27.9	23.8	14.5	8.4	23.6	14.5	9.6	9.6	11.4	15.3	11	11	18.4	10.6
Began Care in First 13 Weeks	85,259	88,054	44	41	120	126	96	90	298	332	114	109	149	150	92	105
Percent Began Care in First 13 Weeks	84.8	84.8	72.1	65.1	82.8	81.8	75.6	72.6	92.5	93.5	81.4	83.2	86.6	87.2	80.7	85.4
Percent Inadequacy of Prenatal Care	9.6	9.4	18	28.6	9	13.6	15	15.3	4.7	4.2	8.6	9.9	7	9.3	12.3	7.3
Infant Death Rate/1,000 Live Births	7.6	7.4	16.4	31.7	13.8	19.5	7.9	0	6.2	11.3	35.7	7.6	0	23.3	8.8	8.1

Brun	swick	Meckle	enburg
2003	2004	2003	2004
170	173	383	325
28	17	35	27
16.5	9.8	9.1	8.3
20.0	14.5	9.9	11.1
136	133	308	219
80	76.9	80.4	67.4
12.9	15.6	12.3	23.7
23.5	11.6	15.7	3.1

The Working Group was chaired by the Secretary of Health and Human Resources and included nearly 40 members who represented all interested parties. The Group was responsible for:

- 1. Reviewing relevant executive branch policies that may serve as an impediment to providing needed care in rural areas of the Commonwealth;
- 2. Developing the executive branch's response to legislatively mandated studies and coordinating the executive branch's response to and work with any other study groups examining similar issues;
- 3. Reviewing best practices in other states; and
- 4. Making policy recommendations as may seem appropriate to the Governor and General Assembly regarding improving access to care in rural areas.

The Working Group issued an interim report and recommended an emergency increase of 34% in Medicaid reimbursement for obstetrical services. This recommendation was implemented in September 2004.

The Working Group issued its final report on October 29, 2004 as House Document No. 52. Among the Work Group's recommendations to improve access to obstetrical care in underserved areas of the state was to establish pilot projects in which certified nurse midwives worked in collaboration with physicians rather than under the supervision of a physician. It was felt that this arrangement would increase the likelihood that certified nurse midwives would practice in the areas that had lost hospital-based obstetrical care and thereby improve access and promote healthy births.

House Bill 2656, enacted by the 2005 General Assembly, authorizes the State Board of Health to approve such pilot projects. A copy of House Bill 2656 is found in Appendix B. Section 1 F. states that "the Department shall evaluate and report on the impact and effectiveness of the pilot programs in meeting the program goals. The evaluation shall include the number of births, the number of referrals for emergency treatment services, successes and problems encountered, the overall operation of the pilot programs, and recommendations for *improvement of the program. The Department shall submit a report to the Joint Commission on Health Care by November 15, 2006, and annually thereafter.*

Progress to Date

Beginning in August 2005, VDH began working with a group of stakeholders from the Northern Neck and Greensville-Emporia areas, including nurse practitioners (certified nurse midwife – CNM) licensed by the Boards of Medicine and Nursing, to explore establishing pilots in these two underserved areas. A list of the stakeholders from these areas is included in Appendix C.

More than a dozen face to face meetings and conference calls have been held that were attended by representatives of the various stakeholders as well as VDH. The focus of these meetings centered on planning, implementing and managing a birthing center, seen as a means to increase access to quality prenatal, delivery, post-partum and pediatric care for Virginia women. The Group explored several well-established certified nurse midwifery care models, including birthing centers in West Virginia and the District of Columbia.

Based upon the guidance provided in HB 2656, stakeholders developed a birthing center pilot program proposal to submit to the Board of Health. This proposal was to include management oversight, financing, protocol development, accreditation, and collaborative agreements between community hospitals, providers and a Level III perinatal care center. One of the most formidable challenges to this process has been securing a means to obtain and maintain professional liability insurance for providers practicing in the proposed birthing center model.

The Board of Health was briefed in October 2005 on the legislation and efforts underway to implement the pilots. The stakeholders made a presentation to the Board of Health in April 2006. The Board of Health reviewed the proposal and requested documentation from the **OB** Pilot Project Report

stakeholders on six items either required by HB 2656 or that the BOH considered integral to assure patient safety. (Correspondence between the BOH and representatives of the pilots is located at Appendix D).

Several stakeholders attended a workshop in November 2005 on "How to Start a Birth Center" sponsored by the National Association of Childbirthing Centers (NACC). Plans for developing the pilot programs were taken from materials presented at this workshop and will be used in the fulfilling criteria for membership in NACC as required by HB 2656.

The General Assembly provided funds for support of the development of birthing centers in the Northern Neck and Emporia areas. An appropriation of \$150,000 in Item 293 #9c (\$75,000 for each of the proposed pilots Northern Neck and Greensville-Emporia) was approved by the 2006 General Assembly. The funds are for FY 2007 only to support start-up of the pilots.

Using the monies appropriated by the 2006 Appropriation Act, a memorandum of agreement (MOA) has been executed between VDH and Virginia Commonwealth University (VCU) to administer these funds (see Appendix E). Stakeholders agreed that it would be best to hire contractors within each community to serve as project coordinators to continue the work of the stakeholders in furthering the building of community partnerships and developing the birthing center business plan.

Each of the two areas has hired a project coordinator to fulfill the required tasks in the MOA. Each project coordinator is expected to establish and develop programs and services leading to a fully operational birthing center in 2008. Coordinator duties include convening a community-based birth center task force for the purposes of networking and building alliances, establishing an advisory council to develop birth center policies and procedures, and developing a project evaluation tool. Consultation and referral mechanisms to assure patients are referred to

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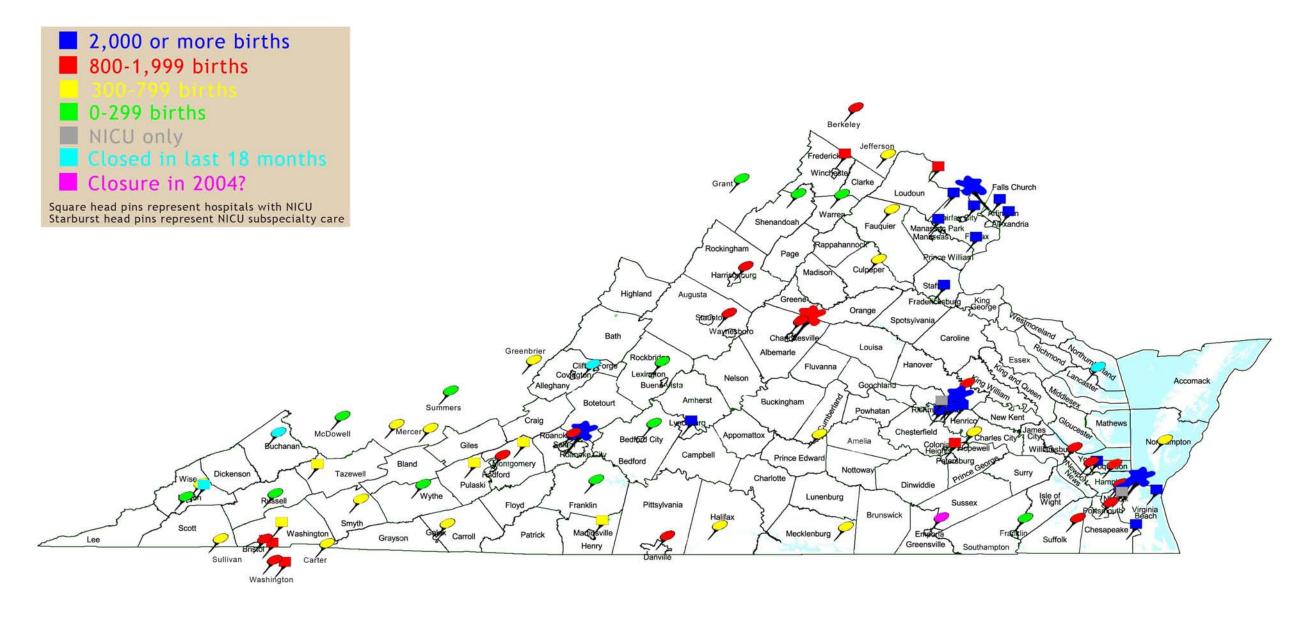
OB Pilot Project Report

the most appropriate provider based on individual risk will be incorporated into the clinical protocols to guide the operation of the pilots to assure high quality care and patient safety. The project coordinators are to work closely with the stakeholders to develop these protocols, write grants and seek other financial resources to support the pilot projects and develop partnerships among agencies within the state that have the mutual goal of increasing access to maternity care of women in Virginia. A complete listing of all expected deliverables is enumerated in the VCU Pilot Birth Center Project Coordinator Work Plan, in Appendix F. VCU has agreed to oversee these contract coordinators and not charge the Department for any indirect costs or other administrative expenses.

The Department will monitor the progress of the pilot projects to provide alternative arrangements for prenatal and delivery services in the Northern Neck and Emporia-Greensville areas. A final report will be submitted to the Governor and General Assembly at the end of project funding, identifying advancements towards improving access to prenatal, obstetrical and pediatric services that have contributed to improving the health and well-being of women, infants, children, and families throughout the Commonwealth.

Finally, it is important to note that, the General Assembly amended the *Code of Virginia* to allow CNMs to practice in a collaborative and consultative role with licensed physicians, rather than being supervised by physicians. Within the next year, the Department of Health Professions will be promulgating regulations based upon the new practice relationship. The removal of the requirement of physician supervision of certified nurse midwives may further expand access to OB care in some areas by increasing the number of providers available to serve low risk pregnant women and their families.

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Virginia Hospitals with Obstetrical Services

2,000 or more births Inova Fairfax Hospital, Falls Church – 10,772 CJW Medical Center (Johnston-Willis and Chippenham), Richmond - 3,851 Inova Fair Oaks Hospital, Fairfax – 3,694 Henrico Doctors' Hospital-Forest, Richmond – 3,671 Mary Washington Hospital, Fredericksburg - 3,327 Inova Alexandria Hospital, Alexandria – 3,326 Virginia Hospital Center, Arlington – 3,218 Chesapeake General Hospital, Chesapeake - 3,057 Carilion Roanoke Community Hospital, Roanoke – 2,730 Sentara Norfolk General Hospital, Norfolk – 2,640 Riverside Regional Medical Center, Newport News - 2,588 Reston Hospital Center, Reston – 2,446 Sentara Virginia Beach General Hospital, Virginia Beach – 2,337 Bon Secours St. Mary's Hospital, Richmond – 2,335 Potomac Hospital, Woodbridge – 2,321 Virginia Baptist Hospital, Lynchburg – 2,315 Sentara Leigh Hospital, Norfolk – 2,158 VCU Health System, Richmond - 2,119 Prince William Hospital, Manassas - 2,058

800-1,999 births

Winchester Medical Center, Winchester – 1,998 Rockingham Memorial Hospital, Harrisonburg – 1,814 Loudoun Hospital Center, Leesburg – 1,777 Martha Jefferson Hospital, Charlottesville – 1,694 University of Virginia Health System, Charlottesville – 1,317 Southside Regional Medical Center, Petersburg – 1,225 Mary Immaculate Hospital, Newport News – 1,159 Bon Secours Maryview Medical Center, Portsmouth – 1,135 Danville Regional Medical Center, Danville – 1,112 Augusta Health Care, Fishersville – 1,057 Obici Hospital, Suffolk – 996 Sentara CarePlex Hospital, Hampton – 962 Bon Secours Memorial Regional Medical Center, Mechanicsville – 912 Bon Secours DePaul Medical Center, Norfolk – 906 Carilion New River Valley Medical Center, Radford – 873 Lewis Gale Medical Center, Salem – 864 Sentara Williamsburg Community Hospital, Williamsburg – 846 WV City Hospital, Berkeley – 897 TN Wellmont Bristol Regional Medical Center, Sullivan – 866 TN Wellmont Holston Valley Medical Center, Sullivan – 1,085 TN Johnson City Specialty Hospital, Washington – 878 TN Johnson City Medical Center Hosital, Washington – 1,379

300-799 births

Johnston Memorial Hospital, Abingdon – 611 Montgomery Regional Hospital, Blacksburg – 596 Memorial Hospital, Martinsville – 560 John Randolph Medical Center, Hopewell – 537 Shore Memorial Hospital, Nassawadox – 500 Halifax Regional Hospital, South Boston – 498 Fauquier Hospital, Warrenton – 493 Community Memorial Healthcenter, South Hill – 375 Twin County Regional Healthcare, Galax – 369 Clinch Valley Medical Center, Richlands – 371

Norton Community Hospital, Norton – 346 Culpeper Memorial Hospital, Culpeper – 341 Southside Community Hospital, Farmville – 311 Smyth County Community Hospital, Marion – 302 WV Bluefield Regional Medical Center, Mercer – 785 WV Jefferson Memorial, Jefferson – 396 WV Greenbrier Valley Medical Center, Greenbrier – 441 WV Princeton Community Hospital, Mercer – 376 TN Indian Path Medical Center, Sullivan – 728 TN Sycamore Shoals Hospital, Carter – 390

0-299 births

Wythe County Community Hospital, Wytheville - 269 Southampton Memorial Hospital, Franklin – 268 Wellmont Lonesome Pine Hospital, Big Stone Gap - 268 Warren Memorial Hospital, Front Royal - 265 Rappahannock General Hospital, Kilmarnock – 254 Stonewall Jackson Hospital, Lexington - 247 Carilion Franklin Memorial Hospital, Rocky Mount - 228 Shenandoah Memorial Hospital, Woodstock - 213 Bedford Memorial Hospital, Bedford - 176 Alleghany Regional Hospital, Low Moor - 169 Southern Virginia Regional Medical Center, Emporia - 168 Buchanan General Hospital, Grundy – 107 Pulaski Community Hospital, Pulaski - 107 Bon Secours St. Mary's Hospital, Norton – 78 Russell County Medical Center, Lebanon - 58 WV Grant Memorial Hospital, Grant - 253 WV Summers County ARH, Summers – 2 WV Welch Community Hospital, McDowell - 101

NICU Only

Children's Hospital, Richmond Children's Hospital of The King's Daughters, Norfolk

NOTE: Hospitals in bold type have NICUs. Hospitals in bold blue type have subspecialty NICUs. Hospitals in bold red type have specialty NICUs. Alleghany Regional Hospital, Bon Secours St. Mary's Hospital, Buchanan General Hospital, Rappahannock General Hospital and Russell County Medical Center have closed their OB facilities in the past 18 months. Southern Virginia Regional Medical Center is unsure on how long it will continue to provide OB services.

Virginia data compiled by Virginia Health Information (VHI) and the Virginia Department of Health.

APPENDIX A

APPENDIX A

COMMONWEALTH OF VIRGINIA



OFFICE OF THE GOVERNOR

Executive Directive 2

Importance of the Issue

Prenatal, obstetrical, and labor and delivery services are a critical component of any modern society's health care system. Prenatal care, obstetrical and labor and delivery services in a community help ensure healthy babies.

A complex combination of factors ranging from third party reimbursement to malpractice insurance premiums has limited the availability of this care in certain rural areas of the Commonwealth. Most recently, this problem has occurred in the Northern Neck, though problems with access to care in rural areas have also developed in Southside and Southwest Virginia.

By virtue of the authority vested in me as Governor under Article V of the *Constitution of Virginia* and under the laws of the Commonwealth, including but not limited to Chapter 1 of Title 2.2, I hereby create the Governor's Working Group on Rural Obstetrical Care.

The Working Group

The working group will initially consist of 17 members. Additional members may be appointed by the Governor at his discretion. The working group will be chaired by the Secretary of Health and Human Resources. The group shall include but shall not be limited to representatives of: the Virginia Hospital & Healthcare Association; the Medical Society of Virginia; the American College of Obstetrics and Gynecology, Virginia Chapter; the Virginia Trial Lawyers Association; and other entities as determined by the Governor. Staff support will be provided by the Office of the Governor, the Office of the Secretary of Health and Human Resources, the Department of Health, and the Department of Medical Assistance Services.

Responsibilities of the Working Group

The working group will be responsible for the following:

- 1) Reviewing relevant executive branch policies that may serve as an impediment to providing needed care in rural areas of the Commonwealth;
- 2) Developing the executive branch's response to legislatively mandated studies and coordinating the executive branch's response to and work with any other study groups examining similar issues;
- 3) Reviewing best practices in other states;
- 4) Making policy recommendations as may seem appropriate to the Governor and General Assembly regarding improving access to care in rural areas.

The working group shall also examine other issues as may seem appropriate.

Reporting Requirements

The working group shall issue a preliminary report to the Governor by July 1, 2004 and a final report to the Governor by October 1, 2004. The preliminary and final reports shall also be provided to the Chairmen of the House Appropriations Committee; the House Committee on Health, Welfare, and Institutions; the Senate Committee on Finance; the Senate Committee on Education and Health; and the Joint Commission on Health Care.

Effective Date of the Executive Directive

This Executive Directive shall be effective upon its signing and shall remain in full force and effect until March 13, 2005, unless sooner amended or rescinded by further executive directive.

Given under my hand this 13th day of March 2004.

Mark R. Warner, Governor

APPENDIX B

Appendix B

CHAPTER 926

An Act to amend and reenact §§ 54.1-2901 and 54.1-2957.01 of the Code of Virginia and to amend the Code of Virginia by adding a section numbered 32.1-11.5, relating to pilot programs for obstetrical and pediatric care in certain areas.

[H 2656] Approved April 6, 2005

Be it enacted by the General Assembly of Virginia:

1. That \$ <u>54.1-2901</u> and <u>54.1-2957.01</u> of the Code of Virginia are amended and reenacted, and that the Code of Virginia is amended by adding a section numbered <u>32.1-11.5</u> as follows:

§ <u>32.1-11.5</u>. Pilot programs for obstetrical and pediatric care in underserved areas.

A. The Board may approve pilot programs to improve access to (i) obstetrical care, which for the purposes of this section includes prenatal, delivery, and post-partum care; and (ii) pediatric care in areas of the Commonwealth where these services are severely limited. The proposals for such pilot programs shall be jointly developed and submitted to the Board by nurse practitioners licensed in the category of certified nurse midwife, certain perinatal centers as determined by the Board, obstetricians, family physicians, and pediatricians.

B. Nurse practitioners licensed by the Boards of Medicine and Nursing in the category of certified nurse midwife who participate in a pilot program shall associate with perinatal centers recommended by the Board and community obstetricians, family physicians, and pediatricians and, notwithstanding any provision of law or regulation to the contrary, shall not be required to have physician supervision to provide obstetrical services to women with low-risk pregnancies who consent to receive care under the pilot program arrangements. Further, notwithstanding any provision of law or regulation to the contrary, a nurse practitioner licensed by the Boards of Medicine and Nursing in the category of certified nurse midwife holding a license for prescriptive authority may prescribe Schedules III through VI controlled substances without the requirement for either medical direction or supervision or a written agreement between the licensed nurse practitioner and a licensed physician. Such perinatal center shall provide administrative oversight by (i) assisting in the development of appropriate clinical care protocols and clinical collaboration, (ii) accepting transfers when necessary, and (iii) providing clinical consultation when requested. Removal of the requirement for physician supervision for participating nurse practitioners licensed by the Boards of Medicine and Nursing in the category of certified nurse midwife shall not extend beyond the pilot programs or be granted to certified nurse midwives who do not participate in approved pilot programs. Further, the removal of the requirement of physician supervision shall not authorize nurse practitioners licensed by the Boards of Medicine and Nursing in the category of certified nurse midwife to provide care to women with high-risk pregnancies or care that is not directly related to a low-risk pregnancy and delivery. Nurse practitioners licensed by the Boards of Medicine and Nursing in the category of certified nurse midwife participating in a pilot program shall maintain professional

liability insurance as recommended by the Division of Risk Management of the Department of the Treasury.

C. The Department shall convene stakeholders, including nurse practitioners licensed by the Boards of Medicine and Nursing in the category of certified nurse midwife, obstetricians, family physicians and pediatricians to establish protocols to be used in the pilot programs no later than October 1, 2005. The protocols shall include a uniform risk-screening tool for pregnant women to assure that women are referred to the appropriate provider based on their risk factors.

D. Pilot program proposals submitted for areas where access to obstetrical and pediatric care services is severely limited shall include mutually agreed upon protocols consistent with evidence-based practice and based on national standards that describe criteria for risk assessment, referral, and backup and shall also document how the pilot programs will evaluate their model and quality of care.

E. Pilot sites that elect to include birthing centers as part of the system of care shall be in close proximity to a health care facility equipped to perform emergency surgery, if needed. Birthing centers are facilities outside hospitals that provide maternity services. Any birthing center that is part of the pilot program shall, at a minimum, maintain membership in the National Association of Childbearing Centers and annually submit such information as may be required by the Commissioner. The pilot programs shall not provide or promote home births.

F. The Department shall evaluate and report on the impact and effectiveness of the pilot programs in meeting the program goals. The evaluation shall include the number of births, the number of referrals for emergency treatment services, successes and problems encountered, the overall operation of the pilot programs, and recommendations for improvement of the program. The Department shall submit a report to the Joint Commission on Health Care by November 15, 2006, and annually thereafter.

§ <u>54.1-2901</u>. Exceptions and exemptions generally.

A. The provisions of this chapter shall not prevent or prohibit:

1. Any person entitled to practice his profession under any prior law on June 24, 1944, from continuing such practice within the scope of the definition of his particular school of practice;

2. Any person licensed to practice naturopathy prior to June 30, 1980, from continuing such practice in accordance with regulations promulgated by the Board;

3. Any licensed nurse practitioner from rendering care under the supervision of a duly licensed physician when such services are authorized by regulations promulgated jointly by the Board of Medicine and the Board of Nursing;

4. Any registered professional nurse, licensed nurse practitioner, graduate laboratory technician or other technical personnel who have been properly trained from rendering care or services within the scope of their usual professional activities which shall include the taking of blood, the

giving of intravenous infusions and intravenous injections, and the insertion of tubes when performed under the orders of a person licensed to practice medicine;

5. Any dentist, pharmacist or optometrist from rendering care or services within the scope of his usual professional activities;

6. Any practitioner licensed or certified by the Board from delegating to personnel supervised by him, such activities or functions as are nondiscretionary and do not require the exercise of professional judgment for their performance and which are usually or customarily delegated to such persons by practitioners of the healing arts, if such activities or functions are authorized by and performed for such practitioners of the healing arts and responsibility for such activities or functions is assumed by such practitioners of the healing arts;

7. The rendering of medical advice or information through telecommunications from a physician licensed to practice medicine in Virginia or an adjoining state to emergency medical personnel acting in an emergency situation;

8. The domestic administration of family remedies;

9. The giving or use of massages, steam baths, dry heat rooms, infrared heat or ultraviolet lamps in public or private health clubs and spas;

10. The manufacture or sale of proprietary medicines in this Commonwealth by licensed pharmacists or druggists;

11. The advertising or sale of commercial appliances or remedies;

12. The fitting by nonitinerant persons or manufacturers of artificial eyes, limbs or other apparatus or appliances or the fitting of plaster cast counterparts of deformed portions of the body by a nonitinerant bracemaker or prosthetist for the purpose of having a three-dimensional record of the deformity, when such bracemaker or prosthetist has received a prescription from a licensed physician directing the fitting of such casts and such activities are conducted in conformity with the laws of Virginia;

13. Any person from the rendering of first aid or medical assistance in an emergency in the absence of a person licensed to practice medicine or osteopathy under the provisions of this chapter;

14. The practice of the religious tenets of any church in the ministration to the sick and suffering by mental or spiritual means without the use of any drug or material remedy, whether gratuitously or for compensation;

15. Any legally qualified out-of-state or foreign practitioner from meeting in consultation with legally licensed practitioners in this Commonwealth;

16. Any practitioner of the healing arts licensed or certified and in good standing with the applicable regulatory agency in another state or Canada when that practitioner of the healing arts is in Virginia temporarily and such practitioner has been issued a temporary license or certification by the Board from practicing medicine or the duties of the profession for which he is licensed or certified (i) in a summer camp or in conjunction with patients who are participating in recreational activities, (ii) while participating in continuing educational programs prescribed by the Board, or (iii) by rendering at any site any health care services within the limits of his license, voluntarily and without compensation, to any patient of any clinic which is organized in whole or in part for the delivery of health care services without charge as provided in § 54.1-106;

17. The performance of the duties of any commissioned or contract medical officer, or podiatrist in active service in the army, navy, coast guard, marine corps, air force, or public health service of the United States while such individual is so commissioned or serving;

18. Any masseur, who publicly represents himself as such, from performing services within the scope of his usual professional activities and in conformance with state law;

19. Any person from performing services in the lawful conduct of his particular profession or business under state law;

20. Any person from rendering emergency care pursuant to the provisions of § 8.01-225;

21. Qualified emergency medical services personnel, when acting within the scope of their certification, and licensed health care practitioners, when acting within their scope of practice, from following Durable Do Not Resuscitate Orders issued in accordance with § 54.1-2987.1 and Board of Health regulations, or licensed health care practitioners from following any other written order of a physician not to resuscitate a patient in the event of cardiac or respiratory arrest;

22. Any commissioned or contract medical officer of the army, navy, coast guard or air force rendering services voluntarily and without compensation while deemed to be licensed pursuant to $\frac{54.1-106}{5}$;

23. Any provider of a chemical dependency treatment program who is certified as an "acupuncture detoxification specialist" by the National Acupuncture Detoxification Association or an equivalent certifying body, from administering auricular acupuncture treatment under the appropriate supervision of a National Acupuncture Detoxification Association certified licensed physician or licensed acupuncturist;

24. Any employee of any assisted living facility who is certified in cardiopulmonary resuscitation (CPR) acting in compliance with the patient's individualized service plan and with the written order of the attending physician not to resuscitate a patient in the event of cardiac or respiratory arrest;

25. Any person working as a health assistant under the direction of a licensed medical or osteopathic doctor within the Department of Corrections, the Department of Juvenile Justice or local correctional facilities;

26. Any employee of a school board, authorized by a prescriber and trained in the administration of insulin and glucagon, when, upon the authorization of a prescriber and the written request of the parents as defined in § 22.1-1, assisting with the administration of insulin or administrating glucagon to a student diagnosed as having diabetes and who requires insulin injections during the school day or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia;

27. Any practitioner of the healing arts or other profession regulated by the Board from rendering free health care to an underserved population of Virginia who (i) does not regularly practice his profession in Virginia. (ii) holds a current valid license or certificate to practice his profession in another state, territory, district or possession of the United States, (iii) volunteers to provide free health care to an underserved area of this Commonwealth under the auspices of a publicly supported all volunteer, nonprofit organization with no paid employees that sponsors the provision of health care to populations of underserved people throughout the world, (iv) files a copy of the license or certification issued in such other jurisdiction with the Board, (v) notifies the Board at least 15 days prior to the voluntary provision of services of the dates and location of such service, and (vi) acknowledges, in writing, that such licensure exemption shall only be valid, in compliance with the Board's regulations, during the limited period that such free health care is made available through the volunteer, nonprofit organization on the dates and at the location filed with the Board. The Board may deny the right to practice in Virginia to any practitioner of the healing arts whose license or certificate has been previously suspended or revoked, who has been convicted of a felony or who is otherwise found to be in violation of applicable laws or regulations;

28. Any registered nurse, acting as an agent of the Department of Health, from obtaining specimens of sputum or other bodily fluid from persons in whom the diagnosis of active tuberculosis disease, as defined in § 32.1-49.1, is suspected and submitting orders for testing of such specimens to the Division of Consolidated Laboratories or other public health laboratories, designated by the State Health Commissioner, for the purpose of determining the presence or absence of tubercle bacilli as defined in § 32.1-49.1; or

29. Any physician of medicine or osteopathy or nurse practitioner from delegating to a registered nurse under his supervision the screening and testing of children for elevated blood-lead levels when such testing is conducted (i) in accordance with a written protocol between the physician or nurse practitioner and the registered nurse and (ii) in compliance with the Board of Health's regulations promulgated pursuant to \$ 32.1-46.1 and 32.1-46.2. Any follow-up testing or treatment shall be conducted at the direction of a physician or nurse practitioner.

B. Notwithstanding any provision of law or regulation to the contrary, a nurse practitioner licensed by the Boards of Nursing and Medicine in the category of certified nurse midwife may practice without the requirement for physician supervision while participating in a pilot program approved by the Board of Health pursuant to $\frac{32.1-11.5}{2}$.

§ <u>54.1-2957.01</u>. Prescription of certain controlled substances and devices by licensed nurse practitioners.

A. In accordance with the provisions of this section and pursuant to the requirements of Chapter 33 (§ 54.1-3300 et seq.) of this title, a licensed nurse practitioner, other than a certified registered nurse anesthetist, shall have the authority to prescribe controlled substances and devices as set forth in Chapter 34 (§ 54.1-3400 et seq.) of this title as follows: (i) Schedules V and VI controlled substances on and after July 1, 2000; (ii) Schedules IV through VI on and after January 1, 2002; and (iii) Schedules III through VI controlled substances on and after July 1, 2003. Nurse practitioners shall have such prescriptive authority upon the provision to the Board of Medicine and the Board of Nursing of such evidence as they may jointly require that the nurse practitioner has entered into and is, at the time of writing a prescription, a party to a written agreement with a licensed physician which provides for the direction and supervision by such physician of the prescriptive practices of the nurse practitioner. Such written agreements shall include the controlled substances the nurse practitioner is or is not authorized to prescribe and may restrict such prescriptive authority as deemed appropriate by the physician providing direction and supervision.

B. It shall be unlawful for a nurse practitioner to prescribe controlled substances or devices pursuant to this section unless such prescription is authorized by the written agreement between the licensed nurse practitioner and the licensed physician.

C. The Board of Nursing and the Board of Medicine, in consultation with the Board of Pharmacy, shall promulgate such regulations governing the prescriptive authority of nurse practitioners as are deemed reasonable and necessary to ensure an appropriate standard of care for patients.

The Board of Medicine and the Board of Nursing shall be assisted in this process by an advisory committee composed of two representatives of the Board of Nursing and one nurse practitioner appointed by the Board of Nursing, and four physicians, three of whom shall be members of the Board of Medicine appointed by the Board of Medicine. The fourth physician member shall be jointly appointed by the Boards of Medicine and Nursing. Regulations promulgated pursuant to this section shall include, at a minimum, (i) such requirements as may be necessary to ensure continued nurse practitioner competency which may include continuing education, testing, and/or any other requirement, and shall address the need to promote ethical practice, an appropriate standard of care, patient safety, the use of new pharmaceuticals, and appropriate communication with patients, and (ii) requirements for periodic site visits by physicians who supervise and direct nurse practitioners who provide services at a location other than where the physician regularly practices.

D. This section shall not limit the functions and procedures of certified registered nurse anesthetists or of any nurse practitioners which are otherwise authorized by law or regulation.

E. The following restrictions shall apply to any nurse practitioner authorized to prescribe drugs and devices pursuant to this section:

1. The nurse practitioner shall disclose to his patients the name, address and telephone number of the supervising physician, and that he is a licensed nurse practitioner.

2. Physicians, other than physicians employed by, or under contract with, local health departments, federally funded comprehensive primary care clinics, or nonprofit health care clinics or programs to provide supervisory services, shall not supervise and direct at any one time more than four nurse practitioners. In the case of nurse practitioners, other than certified nurse midwives, the supervising physician shall regularly practice in any location in which the nurse practitioner exercises prescriptive authority pursuant to this section. A separate office for the nurse practitioner shall not be established. In the case of certified nurse midwives, the supervising physician either shall regularly practice in the location in which the certified nurse midwife practices, or in the event that the certified nurse midwife has established a separate office, the supervising physician shall be required to make periodic site visits as required by regulations promulgated pursuant to this section.

3. Physicians employed by, or under contract with, local health departments, federally funded comprehensive primary care clinics, or nonprofit health care clinics or programs to provide supervisory services, shall not supervise and direct at any one time more than four nurse practitioners who provide services on behalf of such entities. Such physicians either shall regularly practice in such settings or shall make periodic site visits to such settings as required by regulations promulgated pursuant to this section.

F. This section shall not prohibit a licensed nurse practitioner from administering controlled substances in compliance with the definition of "administer" in § 54.1-3401 or from receiving and dispensing manufacturers' professional samples of controlled substances in compliance with the provisions of this section.

G. Notwithstanding any provision of law or regulation to the contrary, a nurse practitioner licensed by the Boards of Nursing and Medicine in the category of certified nurse midwife and holding a license for prescriptive authority may prescribe Schedules III through VI controlled substances without the requirement for either medical direction or supervision or a written agreement between the licensed nurse practitioner and a licensed physician while participating in a pilot program approved by the Board of Health pursuant to § 32.1-11.5.

2. That the Boards of Medicine and Nursing, the Departments of Health Professions and Medical Assistance Services, and the Division of Risk Management of the Department of the Treasury shall provide assistance to the Department of Health in establishing and evaluating pilot programs under this act. APPENDIX C

Stakeholder	Title	Address
Juliana van Olphen Fehr,	Coordinator, Nurse-	Shenandoah University
CNM, PhD, FACNM	Midwifery Education	Winchester, VA
	Program	
	OB Pilot Group	
	Chairperson	
Delores Flowers, MD	Obstetrician	Flower's Woman's Center
		Emporia, VA
Jim Hamilton, MD	Obstetrician	The Maternity Center of
		Northern Neck
		Kilmarnock, VA
Katherine Hedian, CNM	Nurse Practitioner	Crossover Health Center
		Bon Secours Memorial
		School of Nursing
		Richmond, VA
Jessica Jordan, CNM, MSN	Nurse Practitioner	OB/GYN Physicians
		Franklin, VA
		Legislative Liaison
		Virginia Chapter of ACNM
Sharon Jadrnak	Citizen	Emporia-Greensville, VA
Barbara Kahler, MD	Pediatrician	Pediatric Associates
		Richmond, VA
John Seeds, MD	Obstetrician	Department of Obstetricis
		& Gynecology
		Virginia Commonwealth
		University, Richmond, VA
Adolph Flowers, MD	Family Practice	Emporia Medical
		Associates
		Emporia, VA
Cheryl Bodamer, RN, MPH	Coordinator, Central	Virginia Commonwealth
	Commonwealth Perinatal	University
	Council	
Sharon Sheffield, MD	Obstetrician	OB/GYN Associates
		Franklin, VA

Appendix C List of Pilot Project Stakeholder Participants

APPENDIX D



COMMONWEALTH of VIRGINIA

State Board of Health Richmond, Virginia 23219

May 2, 2006

Juliana van Olphen Fehr, PhD Coordinator, Nurse-Midwife Shenandoah University 1775 North Sector Court Winchester, VA 22601

Dear Dr. Fehr:

On behalf of the Board of Health and the State Health Commissioner, I want to thank you and the members of your team for your very thoughtful presentation on April 21, 2006. We appreciate your considerable efforts to bring safe and high quality prenatal and obstetrical care closer to home for pregnant women in the underserved communities of Greensville-Emporia, and in the Northern Neck area. The Board applauds your efforts and your continuing work to implement these plans in your communities.

As promised, I am writing to explain the basis for the Board's decision to ask for further assurances from each pilot project. By way of background, the Board's authority to approve pilot projects in underserved areas was established by HB 2656 enacted by the 2005 General Assembly. This authority is considered permissive in that the Board *may* approve any such pilot project which conforms to the enabling statute. HB 2656 does not prescribe or otherwise limit the Board's prerogative to make reasonable requests for documentation from the pilot projects as a condition for Board approval.

The Board shares your commitment to assuring women in your communities have easy access to safe and high quality prenatal and obstetrical care. It is for this reason that, when approving such a proposal, the Board wants assurances that women who are admitted to and participate in a pilot project, can reasonably expect that if they need more specialized care urgently or if emergency surgery is required, provisions have been made for care consistent with federal and state guidelines and requirements.

The Board is asking that <u>each</u> of the two pilot projects provide written documentation, signed by responsible individuals that include:



Juliana van Olphen Fehr, PhD May 2, 2006 Page 2

- 1. A specific emergency protocol signed by community physicians, hospitals, and the perinatal center, as well as the respective commitment each makes;
- 2. As a representative of the perinatal center integral to the success of the pilots, a letter of commitment from Dr. John Seeds that he has agreed to the specific provisions in HB 2656 for which the perinatal center is responsible;
- 3. A letter from the Chairman of the Board of Directors that the community health center with which you plan to work has applied to HRSA for a change in scope to include the services provided by the pilots;
- A written agreement from the individual physicians who have agreed to provide local physician back-up;
- 5. Documentation of participating nurse practitioners' professional liability insurance;
- 6. Documentation of the status of participating birthing centers' membership in the National Association of Childbearing Centers.

Your proposals for pilot projects pursuant to HB 2656 are the first to come before the Board. Meanwhile, please know that the Board is committed to improving access to safe high quality prenatal and obstetrical services. As we gain experience, there may be future requests for information.

Please contact me or Mr. Jeff Lake if you have any questions or would like additional information.

Sincerely,

Jack O. Lanier, Dr.PH, Chairman State Board of Health APPENDIX E

Appendix E Memorandum of Agreement Between the Virginia Department of Health and Virginia Commonwealth University to Support the Development of Pilot Birth Center Projects within Northern Neck and Emporia-Greensville, Virginia

This Agreement is made the first day of September 2006, by and between the Virginia Department of Health, hereinafter referred to as **VDH**, whose offices are at 109 Governor Street, Richmond, Virginia 23219, and the Virginia Commonwealth University, 800 East Leigh Street, Suite 113, P.O. Box 980568, Richmond, Virginia 23298-0568, hereinafter referred to as **VCU**.

- VDH and VCU both realize that key health indicators show that the many rural regions in Virginia are experiencing an increase in the number of fetal and infant deaths due in part to existing health disparities, long travel times to obtain obstetric care, and lack of insurance;
- VDH and VCU both understand that there are a significant number (estimated 24%) of women of childbearing age who are uninsured, are underinsured or enrolled in Medicaid.
 Between 35 40 percent of Virginia's 100,000 births each year are paid for by the State through its Medicaid program;
- VDH and VCU both recognize that because of decreased access to obstetric care, women with no health insurance, are underinsured, or on Medicaid often delay entry into early prenatal care thus increasing the risk for poor maternal outcomes;

VDH and VCU both believe that in order to address the existing need for prenatal, obstetric and pediatric care that alternative methods of providing care within the mother's community of residence must be developed and VCU desires to serve as project manager during the development of this project,

NOW, THEREFORE, in consideration of their respective experiences, interests and contributions, VDH and VCU hereby covenant to provide the following services:

ARTICLE I - SCOPE OF SERVICES

VCU agrees to:

Select two highly qualified, advanced practice nurses to serve as the Birth Center Project Coordinators for the Northern Neck and the Emporia-Greensville areas.

- 1. Summary of knowledge, skills and abilities needed to serve as the project coordinator are as follows:
 - a. Strong interpersonal and human relations skills demonstrated through coordinating and networking with health care, business and like-minded community service providers.
 - b. Knowledgeable on maternal/child health care needs of the under-served population.
 - c. Demonstrated leadership in working with diverse groups and building alliances
 - d. Experienced in obtaining external funding support such as grants, innovative funding sources, including capital development projects
 - e. Ability to lead a multidisciplinary team to meet established goals.

2. Each Project Coordinator agrees to fulfill the duties and responsibilities as delineated in the scope of services for the agreed upon rate of reimbursement specified in the conditions of employment. (Refer to Appendix F for Chart of Required Tasks and Subtasks & Time line for Accomplishment by Project Coordinator)

Provide office space, office equipment and office materials and supplies as required by each project coordinator to conduct administrative duties associated with fulfilling the terms of this agreement and as permitted by budget and facility resources availability.

Provide use of a conference room or other available space as necessary for convening the public and private task force members and advisors serving to develop a community based birth center.

Provide project management oversight to ensure that all components in the scope of service area satisfactorily completed within the given timeframes and quarterly reports are submitted as required. The deliverables for the project manager are as follows:

Notify VDH of any problems in fulfilling any of the terms of this Agreement so that solutions can be developed or alternative arrangements can be made.

Provide quarterly written updates, beginning in December 2006 with a final written report due by June 30, 2007.

VDH and VCU agree to:

1. VCU's Program Director serving as the project manager.

- 2. Adhere to the established work plan and time schedule (Appendix A) for completion of the various components of the project.
- 3. Collaborate to maintain a summary of all activities funded to this agreement to aid in the evaluation of the efforts of this work funded by this agreement.

VDH agrees to:

Provide a primary contact for purposes of collaborating on the implementation of project tasks and priorities.

- Provide additional technical assistance or advice that may be required for purpose of expediting the project.
- Provide the funding for this project in an amount not to exceed \$75,000 in each of the two pilot areas.

ARTICLE II - BUDGET

VCU's budget for providing services to VDH during the term of this Agreement is limited to \$75,000, for each pilot area which includes:

Project Coordinator Compensation	\$69,700
NACC Birth Center membership Application fee	\$800
Marketing & Curriculum Materials	\$4,500

Total:	\$75,000
Total for Two Pilot Projects	\$150,000

This budget only includes VDH's obligation to VCU. It is understood that VCU will contribute in-kind services to fulfill the obligations of this Agreement enumerated above.

ARTICLE III - TERM OF AGREEMENT

The services of VCU shall commence on September 1, 2006 and shall terminate at the close of business on June 30, 2007. Notwithstanding the foregoing provision, either party as provided in the section entitled "Termination" may terminate this Agreement.

ARTICLE IV – REPORTING

Interim reports itemizing expenditures according to the project within the Scope of Services will be submitted to VDH at three-month intervals of the contract. A final expenditure report will be submitted to VDH by June 30, 2007.

ARTICLE V - COMPENSATION

VDH shall reimburse VCU for actual expenditures made as a result of services performed under the terms of this Agreement based on the budget submitted by VCU and as approved by VDH. VCU shall bill VDH on a regular basis by invoice with supporting documentation and citing the contract number assigned. Billing shall be due based on the following schedule:

1st Period – September 1, 2006 through December 30, 2006 – by January 15, 2007

2nd Period – January 1, 2007 through March 31, 2007 – by April 15, 2007

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3<sup>rd</sup> Period – April 1, 2007 through June 15, 2007 – by June 30, 2007
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Invoices should be addressed to:

Joanne Wakeham, RN, Ph.D. Virginia Department of Health 109 Governor Street, 13th floor Richmond, Virginia 23219

ARTICLE VI - GENERAL PROVISIONS

Nothing in this Agreement shall be construed as authority for either party to make commitments, which will bind the other party beyond the Scope of Services, contained herein. Furthermore, VCU shall not assign, sublet, or subcontract any work related to this Agreement or any interest he/she/it may have herein without the prior written consent of VDH. This Agreement is subject to appropriations by the Commonwealth and the Federal government.

ARTICLE VII - SPECIAL TERMS AND CONDITIONS

When providing the services specified under this agreement, VCU shall not be deemed an "employee" or "agent" of the Virginia Department of Health. VCU shall act as an independent contractor and is responsible for obtaining and maintaining appropriate liability insurance, payment of all FICA, State and Federal taxes, and complying with other similar requirements, which are customary in the industry.

Funding available from this Agreement shall not be used for lobbying activities. Recipients of Federal funds are prohibited from using those funds for lobbying for or against legislation pending before the Federal Government or State legislatures.

VCU and any employee hired under this agreement shall adhere to the confidentiality provisions contained in Title 32.1 of the Code of Virginia.

VCU shall submit to VDH, for prior approval, all educational materials (i.e. videos, pamphlets) to be purchased or developed for which VDH's financial support is used.

VCU agrees to obtain prior approval from VDH for any modifications to the budget greater than five percent in any category.

As an instrumentality of the Commonwealth of Virginia, VCU is self-insured, as prescribed by the Code of Virginia and resulting regulations. We offer the following insurance statement. VCU agrees to be responsible, where found liable and to the extent covered by insurance or specified by statute, whichever is lower, for the payment of any or all claims for loss, personal injury, death, property damage or otherwise arising out of any act or omission of its employees or agents. VCU is covered by a self-insured plan based on a comprehensive general liability manuscript form as authorized by the Code of Virginia.

A copy of VCU's current insurance Certificate of Coverage is available and attached to this agreement.

ARTICLE VIII - TERMINATION

This Agreement may be terminated prior to the expiration of the term on June 30, 2007 as follows:

- A. By mutual agreement of the parties; or
- B. By either party, with or without cause, upon 30 days written notice to the other; or
- C. By VDH, by reason of material breach by VCU. In such event, VDH shall have the right immediately to rescind, revoke or terminate this Agreement. In the alternative, VDH may give written notice to VCU specifying the manner in which the Agreement has been breached. If a notice of breach is given and VCU has not substantially corrected the breach within 30 days of receipt of the written notice, VDH shall have the right to terminate this Agreement.

In the event of termination, VDH shall pay the VCU all monies due and owing as provided in the section "Compensation," such monies to be calculated on a pro rata basis for services rendered by the VCU through the date of termination plus any non-cancelable items.

ARTICLE IX - RENEWAL

Non-renewing funding.

ARTICLE X - FINANCIAL RECORDS

VCU agrees to retain all financial books, records and other financial documents relative to this Agreement for five (5) years after final payment, or until audited by the Commonwealth of Virginia, whichever is earlier. VDH its authorized agents, and/or State auditors shall have full access to and the right to examine any of said materials during said period.

VCU shall comply with the audit and reporting requirements defined by the Federal Office of Management and Budget (OMB) Circular A-133 (Audits of States, Local Governments, and Non-Profit Organizations) as applicable.

As a condition of receiving funds, the independent auditor shall have access to all records and financial statements as may be necessary under the circumstances; and, all personnel costs allocated to this Agreement must be substantiated by individual records of staff percentage of effort, in the form of signed certification by staff reflecting effort devoted to this Agreement in accordance with OMB Circulars A-21 and A-110. Certification must be signed by the employee's supervisor and maintained on file for audit purposes. All audits are to be conducted within one year of the close of the grant fiscal year end in accordance with the Standards for Audit of Governmental Organizations, Programs, Activities, and Functions issued by the Comptroller General. The VCU must also submit their audit report and corrective action plan, if applicable, to VDH within thirty days after the completion of the audit report. Failure to provide an audit report within the specified time period or failure to complete corrective actions will be considered a breach in the terms of the contract, and as such, may lead to termination of the grant or discontinuation of future funding until such time as an audit report is provided.

ARTICLE XI - PROPERTY ACQUISITION/MANAGEMENT*

The budget is not approved for the purchase of equipment.

ARTICLE XII - OWNERSHIP OF INTELLECTUAL PROPERTY

All copyright and patent rights to all papers, reports, forms, materials, creations, or inventions created or developed in the performance of this Agreement shall become the sole property of the Commonwealth.

VCU hereby grants a royalty-free, non-transferable, non-exclusive license to VDH to make and/or use for its lawful non-commercial purposes any product which is covered by a patent resulting from work conducted under this Agreement, for the life of such patent. Should the Federal government have any interest in such a product by virtue of its providing to VDH or VCU part or all of the funds involved in this Agreement, it shall receive such rights as are provided for by law or regulation. Both VDH and VCU shall notify the other of the existence of such Federal government rights immediately upon receipt of disclosure of an invention.

ARTICLE XIII - NOTICES

Any notices required or permitted hereunder shall be sufficiently given if hand delivered or if sent by registered or certified mail, postage prepaid, addressed or delivered to VCU's principle contact for program and/or to Deputy Commissioner for Community Health Services, Virginia Department of Health, 109 Governor Street, 13th floor, Richmond, Virginia 23219.

ARTICLE XIV - INTEGRATION AND MODIFICATION

This Agreement constitutes the entire understanding of the parties as to the matters contained herein. No alteration, amendment or modification of this Agreement shall be effective unless in writing and signed by the duly authorized officials of both VDH and VCU.

ARTICLE XV - ASSIGNMENT

VCU shall not assign, sublet, or subcontract any work related to this Agreement, or any interest it may have herein, without the prior written consent of VDH, and nothing in this Agreement shall be construed as authority for either party to make commitments which will bind the other beyond the terms of this Agreement.

ARTICLE XVI - SEVERABILITY

If any provision of the Agreement is held to be invalid or unenforceable for any reason, this Agreement shall remain in full force and effect in accordance with its terms, disregarding such unenforceable or invalid provision.

VCU certifies that he/she/it has not employed or retained any person or persons for the purpose of soliciting or securing this Agreement. VCU further certifies that he/she/it has not paid or agreed to pay any other consideration, contingent upon the award of this Agreement. For breach of one or both of the foregoing warranties, VDH shall have the right to terminate this Agreement without liability, or in its discretion, to deduct from the agreed fee, payment or consideration, or otherwise recover, the full amount of said prohibited fee, commission, percentage, brokerage fee, gift, or contingent fee.

ARTICLE XVII - CAPTIONS

The caption headings contained herein are used solely for convenience and shall not be deemed to limit or define the provisions of this Agreement.

ARTICLE XVIII - WAIVER

Any failure of a party to enforce that party's rights under any provision of this Agreement shall not be construed or act as a waiver of said party's subsequent right to enforce any of the provisions contained herein.

ARTICLE XIX - TESTING AND INSPECTION

VDH reserves the right to conduct any reasonable test and/or inspection of the VCU's facilities it may deem advisable to assure services conform to the specifications.

ARTICLE XX - GOVERNING LAW

This Agreement shall be governed in all respects by the laws of the Commonwealth of Virginia, and any litigation with respect thereto shall be brought in the Circuit Court of the City of Richmond, John Marshall Courts Building, unless waived by VDH.

APPROVED BY:

Virginia Commonwealth University

By: _____ (Signature)

Susan E. Robb, CRA, Director

Office of Sponsored Programs

Date

FIN Number: ____54-6001758_____

Attachment: Appendix F

By: ______(Signature)

Jeffrey Lake, Deputy Commissioner

Virginia Department of Health

Virginia Department of Health

Date

APPENDIX F

APPENDIX F VCU Pilot Birth Center Project Coordinator (PC) Work Plan For Virginia Department of Health September 2006-July 2007

	Virginia Department of free	1	Sept	Dec	Mar	June
Tasks+ & Subtasks±	Deliverable	Assigned	Oct	Jan	April	
		8	Nov	Feb	May	
+Review the Northern Neck community health assessment focused on maternal/child health indices of need.	• Summary of updated health care needs of under-served targeted population.	PC	*			
+Contact the National Association of Childbearing Centers (NACC) to request application package and seek technical assistance in starting a birth center in NN.	• Copy of completed NACC application with submission date	PC	*			
Review all background documents related to the development of birthing centers in Virginia to include the <i>Final Report of the Governor's</i> <i>Workgroup on Rural Obstetrical</i> <i>Care, HB 2656, Plan for Pilot Project</i> <i>Birth Center for Emporia and the</i> <i>Northern Neck, Virginia April 21,</i> <i>2006</i> and the Board of Health's Recommendations to OB Pilot group dated April and July 2006. Review <i>How to Start A Birth Center</i> manual published by the NACC, 2005.		PC	*			

Tasks+ & Subtasks±	Deliverable	Assigned	Sept Oct Nov	Dec Jan Feb	Mar April May	June
+Convene community-based birth center task force for purposes of networking and building alliances. ± Task force to assist with donor fundraising, identifying and attracting external financial support and sources of capital funding for project expenses ±Obtain support from community to secure appropriate space for birth center operations ±Conduct focus groups to develop birth center services marketing plan ±Develop birth center services marketing plan	 Roster of task force members & meeting minutes. Documented requests to funding sources Agency listing of community support match Summary of focus group recommendations, list of participants, and written marketing plan. 	PC		*	*	*

Tasks+ & Subtasks±	Deliverable	Assigned	Sept Oct	Dec Jan	Mar April	June
		U	Nov	Feb	May	
 +Establish an advisory council comprised of community health care providers (physicians, nurse practitioners, hospital administrators, public health practitioners), social service representatives, and health care insurance representatives to include the Department of Medical Services to begin development of the birth center policy and procedure manual. ±Develop birth center medical protocols to include: Eligibility document Community specific uniform prenatal risk assessment tool addressing the management of high risk pregnant women and required signatories. CNM clinical protocol ±Develop an MOA specifying the referral and back-up agreements between and among all involved obstetric providers and facilities ±Develop an emergency protocol for handling complicated deliveries signed by community physicians, community hospitals and perinatal center director 	 Listing of advisory council members Birth center eligibility document established Community specific uniform prenatal risk assessment tool addressing high risk management of OB patients developed and signed by all agents. CNM protocol MOA specifying referral and back-up between and among obstetric providers and facilities signed by all agents. Emergency protocol for handling complicated deliveries signed by all agents. 	PC	*	*	*	

Tasks+ & Subtasks±	Deliverable	Assigned	Sept Oct Nov	Dec Jan Feb	Mar April May	June
+Develop an evaluation tool based upon the NACC Uniform Data Set to include all requirements stipulated in HB2656.	 Computerized spreadsheet of indices to track perinatal outcomes and outputs. 	PC			*	
+Seek grant opportunities for start-up costs of birthing center	 Listing of funding sources, and applications submitted 	PC		*	*	
+Identify coverage options for providers ± Identify professional liability insurance requirements and rates for nurse practitioners, and physicians ±Identify liability insurance requirements and rates for ancillary staff, consulting staff and facility		PC PC			*	
Ensure that all components in the scope of service area satisfactorily completed within the given timeframes and quarterly reports are submitted as required	• Required reports submitted on time.	PC	*	*	*	*

			Sept	Dec	Mar	June
Tasks+ & Subtasks±	Deliverable	Assigned	Oct	Jan	April	
			Nov	Feb	May	
Collaborate with VDH to maintain a		PC	*	*	*	*
summary of all activities funded to						
this agreement to aid in the evaluation						
of the efforts of this work funded by						
this agreement						