

APPENDIX A

NEW CONTRACEPTIVE METHODS THAT ARE NOT AVAILABLE UNDER THE GEORGIA FAMILY PLANNING PROGRAM OR ARE PROHIBITIVELY EXPENSIVE UNDER INSURANCE OR GEORGIA MEDICAID

According to the first government estimate on childbirth expenses, the average cost of having a baby in the United States, *if there are no complications*, is about \$7,600.ⁱ The upfront cost of each of these methods must be weighed against the enormous costs to Georgia taxpayers of not providing the method:



The FDA approved the MIRENA IUSⁱⁱ in 2000. Mirena is a "Tier One" birth control method. This IUD is a hormone-releasing system that is placed into the uterus by an APRN (Advanced Practice Registered Nurse) or MD to prevent pregnancy for at least 5 years. Mirena but it has multiple other benefits. Mirena treats heavy menses and associated menstrual cramping, which allows for better school and work attendance (as opposed to the Paragard-the only IUD on the state formulary, is an excellent IUD, but induces heavier menses and cramping in some women). The Mirena improves anemia, may protect against endometrial cancer, and decreases the chance of having an ectopic pregnancy (No.1 death risk for black women in the 1st trimester). The Mirena also decreases the need for several surgeries including D&C, hysterectomy and surgery for fibroids. This is of particular importance since Georgia has significantly higher incidences of hysterectomy than other regions of the country; those surgeries are most likely to be performed on women of childbearing age.ⁱⁱⁱ The IUS is easily removed and the woman has a quick return to fertility if desired. The upfront cost to a Title X clinic is \$345 but over a five (and possibly seven) year period the actual monthly cost of an IUS is \$5.75. Further, the Mirena has an established foundation^{iv} to allow indigent clients to apply for a free IUS. Mirena has an established program (the ARCH Foundation) which provides the device free to low income women. By not placing the Mirena on the GFPP formulary, Georgia public health forces the few clinics that are providing this method to drain the resources of the ARCH Foundation.



The Implanon^v is a match sized flexible plastic capsule that is inserted under the skin of a woman's upper arm. The Implanon provides contraception for at least 3 years and is a "Tier One" birth control method. Implanon's efficacy is essentially indistinguishable from that of sterilization and intrauterine devices.⁴ Implanon is particularly suitable for women who desire safe, extremely effective, long-term, maintenance-free, and reversible contraception. ImplanonTM can only be ordered, inserted, and removed by a healthcare

provider that has been trained in a manufacturer-sponsored training program, which will optimize patient care and minimize the already rare complications. Once the Implanon is inserted, no other action is required by the woman for at least three years. The 340B Drug Pricing Program slashes the cost of the implant by 50% for Title X clinics, making the upfront cost only \$289, or a monthly cost of \$8.06. Studies of actual use in the clinic setting show that continuation rates of Implanon is high,^{vi} making the Implanon a very cost-effective contraceptive. Like the Mirena, the availability of Implanon is of special importance to women who cannot use a contraceptive that contains estrogen. Further, both the Implanon and Mirena require a limited number of nursing or office visits, (12 visits are required over 3 years for Depo-Provera usage vs. two for either the Implanon or Mirena), making either method ideal for adolescents and low-income women who have transportation problems. One public health clinic in Rome, Georgia has inserted fourteen Implanon for its clients, and to date, all have continued the method.^{vii} Training programs are widely available and free to any provider who desires training, but few public health providers have received the training and the device has not been offered by the GFPP. Further, the Medicaid reimbursement for these methods of birth control is good and placing one implant or IUD for a Medicaid client pays enough to pay for one method for the next indigent client. Private practices, for monetary reasons, will have an incentive to advocate for contraceptive options for women, public health must take the lead to advocate for these effective methods for low income women.



Essure^{viii} is a "**Tier One**" birth control method that is a permanent and hormone free sterilization method. It is different from traditional method of a surgical tubal ligation because no surgical incisions are required. Instead, an Essure trained doctor inserts spring-like coils, called micro-inserts, into a woman's fallopian tubes through the vaginal route. The procedure is performed as an office procedure without general anesthesia. After a three month period, a test is done to ensure that the tubes are blocked. The effectiveness of Essure is 99.95% at 1 year, versus 99.45% at 1 year for traditional surgical sterilization. The Essure procedure is covered by most insurance companies and is covered under Georgia Medicaid. However, this procedure remains unavailable to most Medicaid patients because of the non-existence of a family planning Medicaid waiver and rapid cancellation of Georgia Medicaid following delivery. Georgia Medicaid is typically cancelled within 8 weeks after delivery, making the follow-up 3 month testing (**hystosalpingogram**) prohibitively expensive.



The FDA approved the **Nuvaring** in 2001. Nuvaring is a "**Tier Two**" birth control method and is a flexible, transparent, colorless vaginal ring about 2.1 inches in diameter. The Nuvaring contains hormones which are similar to the active ingredients in some birth control pills. The Nuvaring is inserted by the woman and it releases a continuous low dose of the hormones. A new ring is used each month for continuous contraception. The benefits of Nuvaring include blood levels of estrogen that are lower than

either the Ortho Evra patch or combined birth control pills, thus women with risk factors such as hypertension and obesity who want to use combined contraceptives may be safest with the Nuvaring. There are no daily fluctuations in hormonal levels and this results in better cycle control and less discontinuation of the method for breakthrough bleeding. There are few reported estrogenic side effects that typically cause pill discontinuation such as nausea, headache and breast tenderness. Nearly all users are satisfied, so the continuation rates are improved. The public health price of the ring is less than \$15.00 per month.



The FDA approved the first transdermal drug delivery contraceptive patch for use on a weekly basis in 2002. The Ortho Evra^{ix} Patch is applied by the user on the same day each week for three consecutive weeks. The benefits of the Patch include better cycle control and the once a week dosing which increases compliance. Despite initial concerns that the patch may increase the risk of deep venous thrombosis (DVT), large follow-up studies show that the risk of nonfatal VTE for the contraceptive patch is closely similar to other birth control pills^x and the DVT risk is far lower than the DVT risk associated with pregnancy. The public health price of the Patch is less than \$15.00 per month.

Low dose and extended use oral contraceptive pills: There are several low dose (but identical effectiveness) new oral contraceptives on the market and the current medical recommendation is to place a woman on the lowest estrogen dose pill possible. But, there is no low dose (20 mcg.) pill on the GFPP. In addition, new and very popular pills (Seasonale,^{xi} Seasonique and Lybrel) allow for safe, easier and extended menstrual manipulation (skipping menses for 3 months to up to one year). The effectiveness and safety is the same, the serious risks are the same, but it allows for a woman to be in control of when or how often she wishes to have a period. While there is one pill on the GFPP formulary that can be taken in an extended use fashion, there is no dedicated product for this use, nor is there a protocol available to allow nurses in the GFPP to counsel patients in this new use of an old method.