Chapter Five

Prescription Drugs

Prescription drugs are a critical component of healthcare. More than 40% of all Americans take at least one prescription drug, and 17% take three.[1] Yet many people lack the necessary means to purchase needed medications. Nationally, 23% of non-elderly Americans lacked drug coverage in 1996 (most recent data available); 36% of Medicare recipients lacked coverage in 2001.[2] Medicare Part D—to be implemented in January 2006—should make drug coverage more available to Medicare recipients, particularly those with low incomes who can qualify for Medicare Part D with little or no cost-sharing. However, the uninsured, as well as some with private health insurance, lack coverage for prescription drugs. Lack of insurance coverage often translates into difficulty purchasing medications. A 2003 Kaiser health insurance survey found that 37% of the uninsured said that they did not fill a prescription because of costs, compared to 13% of people with insurance coverage.[3] Lack of prescription drug coverage is a particular problem for people with chronic illnesses, and thus they have an ongoing need for medications to manage their health problems, but the problem is not limited to this population. The health of any individual may be compromised by the inability to obtain needed medications.

There are some limited resources available to the uninsured (or others who lack prescription drug coverage), but like other safety net services, these resources are not available in every community. The largest source of free medications is through patient assistance programs, offered by pharmaceutical companies. Each manufacturer determines which drugs will be offered through their program and sets specific eligibility requirements. Thus, the uninsured are not always assured medications through these programs. Some of the safety net providers also offer free or low-cost medications (or assist patients in filling out the necessary forms to obtain the free drugs through the patient assistance programs). In addition, a few communities have organized local pharmacy assistance programs, to help low-income uninsured patients obtain needed medications. Low-income Medicare recipients have other sources of assistance—either through the Medicare—sponsored pharmacy discount cards and/or the Senior Care program. These programs are described more fully below.

Patient Assistance Programs (PAP)

Patient Assistance Programs (PAPs) are programs offered through pharmaceutical manufacturing companies that provide free or low-cost medications to certain low-income individuals.[4] In 2004, there were 75 company-sponsored programs that covered approximately 1,200 different medications.[5] According to the Pharmaceutical Research and Manufacturers of America (PhRMA), the PAP programs helped 6.2 million uninsured or underinsured individuals obtain more than 17.8 million prescriptions nationally in 2003. In the same year, 270,516 North Carolinians accessed medications through these programs.[6,7]

The PAP programs vary substantially from one another in terms of the medications offered, eligibility requirements, and application process. Some require eligible individuals to reapply each month; others will accept one application to cover medications for longer periods of time. All PAPs have income requirements and exclude individuals with healthcare insurance coverage, unless the individual lacks prescription drug coverage (for example, some of the PAPs will provide assistance to people with Medicare if they do not have supplemental coverage that covers medications). Some PAPs are limited to persons with certain diseases, while others are broader in scope. The application process can be laborious. Most of the programs require extensive documentation of financial resources (some require that a patient provide copies of their tax returns), and many require that the patient exhaust other alternatives for prescription drug coverage (i.e., they must first apply for Medicaid). For some, the application is available online, but others require an interested party to request an application by phone or fax. Typically, the programs require a healthcare provider or a social worker to initiate the application process, and most

require the physician's signature on the application. Some of the companies will ship bulk prescriptions to safety net organizations so that they have medications on-hand to meet the immediate prescription drug needs of their patients, others require that medications be shipped individually to the provider and/or the patient. Furthermore, the programs are not always consistent because pharmaceutical companies sometimes vary the drugs covered, eligibility requirements, or application process.

In light of these challenges, the Task Force recommends:

Rec. 5.1. The NC Office of Research, Demonstrations and Rural Health Development and other safety net organizations should create a workgroup to meet with pharmaceutical companies to discuss:

a) Simplifying and streamlining the Patient Assistance Programs, including the application forms, verification requirements, and eligibility requirements; and

b) Creating bulk replenishment programs and other ways the pharmaceutical industry could help provide medications to safety net organizations.

Information should be disseminated to safety net organizations and private physician practices about the best way to access existing pharmaceutical resources.

As just noted, the variation in these programs makes it very difficult and time-consuming to identify helpful programs and apply for them. It is often difficult for private physicians' offices as well as some smaller safety net programs to take advantage of these free medications, because of the program complexity. There are several programs available to help providers, advocates, and patients access PAP medications. For example, Pharmaceutical Research Manufacturers of America has its own internet-accessible computer system to help providers and patients determine eligibility for medications provided by PAPs.[8] The NC Foundation for Advanced Health Programs, Inc., with funding from The Duke Endowment, also developed software to assist providers and advocates in accessing appropriate PAP programs. The Medication Access and Review Program (MARP) is software being used in about 80 sites in North Carolina, including federally qualified health centers (FQHCs), rural health centers, health departments, free clinics, Area Agencies on Aging, senior centers, hospitals, non-profit pharmacy assistance programs, and Healthy Carolinian projects. The Office of Research, Demonstrations, and Rural Heath Development (ORDRHD) provides technical assistance to support communities in using the MARP software. MARP supports two programs: the basic program that identifies appropriate PAPs and a more sophisticated program known as 'medication management programs,' which involves pharmacotherapy review. The basic program includes information on all current PAP programs, their eligibility requirements, and application forms. Once patient information is entered into the system, the computer will self-populate all the appropriate fields so that the same information need not be re-entered every time the patient needs a new medication or refill. The medication management pro-

Crisis Control Ministry Pharmacy (CCMP)

Crisis Control Ministry is a non-profit organization in Forsyth County that offers a pharmacy assistance program. Crisis Control Ministry Pharmacy (CCMP) is staffed by one full-time pharmacist, a pharmacy technician, a pharmacy assistant, and more than 150 volunteers. To qualify for medications people must lack income to pay for their medications. CCMP served 2,600 people and dispensed 31,351 prescriptions in 2003 (totaling more than $2.0 million in medications). The staff helps clients apply for the pharmacy assistance programs offered by pharmaceutical companies. Medications for eligible clients are shipped to CCMP where the patients receive the medications and prescription drug counseling. Some pharmaceutical manufacturers also provide bulk shipments to CCMP for a group of patients (which is easier administratively than applying for and receiving separate medications). CCMP also receives donated pharmaceuticals from local physicians and nursing homes. Volunteers help to repackage the medications into larger bottles, so that they can be dispensed by the pharmacist. CCMP has limited funds to purchase medications that are not available through PAPs or donations. In 2003, CCMP spent $200,000 to buy needed medications. CCMP is not eligible for 340B discounted drug prices.

gram requires coordination with at least one area pharmacist and helps assess possible drug interactions, provides patient and provider education, and offers counseling on alternative therapies.

The MARP system has helped providers and non-profit agencies access patient assistance programs, but some organizations have been unable to use this software. The primary obstacle is that many of the sites lack adequate technology or personnel to operate the software.

The software itself is free to sites, and training on how to use the program is also provided free of charge by the ORDRHD. Furthermore, the software is fairly easy to navigate and can be operated by a staff person who has been trained as a prescription assistance coordinator (PAC). However, the site must have a computer with Windows 2000 or XP, Office 2000 (or a more current version), a good printer, networking capability, and a compatible server to run MARP. In some sites, firewalls have prevented the software from operating correctly because the security protections prevent essential update downloads on the drug discount programs.

To address this barrier, the NC Health and Wellness Trust Fund Commission (HWTFC) provided funding to the ORDRHD to help fund and provide technical assistance to community agencies to create or expand existing medication assistance programs and provide funds to purchase the necessary hardware. Since 2002, 69 grants were awarded (through a request for proposals process) to sites serving 95 counties, to implement the software and to establish medication assistance programs that extend pharmacist-provided drug management to patients.[9] These grants provide start-up funding to recipients for up to three years while sustainability is established. The UNC School of Pharmacy provides assistance to the remaining counties through telephone consults.

Some of these programs, like Senior PharmAssist in Durham, were initially created to assist seniors. Other programs provide assistance to low-income individuals of all ages who lack prescription drug coverage. In addition, those that were initially established to serve older adults are being encouraged to expand their scope of services to the population under age 65 years because most low-income seniors will soon be covered by Medicare Part D. While these programs provide critical services, they are unable to help every low-income uninsured patient. Between January 1 and November 30, 2004, the MARP software was used to help 24,973 patients access PAPs. Staff in different organizations helped patients submit 64,796 new requests for medications and 55,116 reorders.

Currently, funding from the HWTFC is sufficient to support the existing programs through 2008 and to provide for modest expansion. However, in the past, the NC General Assembly has taken some of the funding from the HWTFC to support other healthcare initiatives. Funding for local medication assistance programs and support of the MARP system may be insufficient if the HWTFC has inadequate funds to support these programs. Therefore, the Task Force recommends:

Rec. 5.2. The NC General Assembly should support the Health and Wellness Trust Fund's efforts to support and expand prescription assistance programs, including, but not limited to, expanding the availability of Medication Access and Review Program (MARP) and medication assistance programs.

In addition to the existing PAPs, in January 2005, ten major pharmaceutical companies announced a new prescription drug discount card, called Together Rx Access™ for certain individuals who lack prescription drug coverage.[10] To qualify, an individual must:

- Be under age 65 years and not otherwise eligible for Medicare,
- Have no other public or private prescription drug coverage,
- Have an income that is equal to or less than 300% of the federal poverty guidelines, and
- Be a documented US resident.

Together Rx Access™ promises savings of between 25-40% on more than 275 brand-name medicines and other generic products. While these savings are important, many uninsured individuals will still need access to the PAP programs, as the discounted price of certain medications may still be unaffordable. The new discount program promises to notify individuals if they would be eligible for free or further discounted medications through the PAPs.

Medications Available through Safety Net Providers

Many of the safety net providers discussed in Chapter 3 also help their patients obtain prescribed

medications. Most safety net programs assist uninsured patients in obtaining free or reduced cost pharmaceuticals through the PAPs. However, PAPs do not cover the medication needs of all of the uninsured. Even when medications are available through a PAP, the safety net provider may need to provide an immediate short-term supply until the patient's PAP application is approved, and medications are sent in the mail. As a result, some safety net organizations have developed systems to assist patients in obtaining medications when they are unable to do so through the PAP. These systems vary, depending on the type of provider and available resources. For example, smaller free clinics are typically more limited in the types of medications they can offer because they may rely on donated medications from local physicians' offices and/or nursing homes. Ten communities in the state have created free pharmacies—similar to free clinics—that focus exclusively on meeting the medication needs of low-income uninsured residents. The free pharmacy clinics generally have a larger array of available medications than smaller free clinics, and may purchase some medications in addition to the medicines dispensed through donations or received through the PAPs. However, these organizations typically have limited ability to purchase medications due to the high cost of pharmaceuticals. Hospitals and some of the larger FQHCs and health departments provide medications through in-house pharmacies.

Private physicians' offices and rural health centers do not always have the staff needed to fill out PAP applications. Many communities have non-profit organizations that help people access the PAPs and provide medication counseling.

The 340B Drug Discount Program

Some of the safety net organizations have access to deeply discounted medications through the 340B program. The 340B program is a federal program that provides eligible safety net programs with discounts on drugs.[i] The program originated as Section 602 of the Veteran's Health Care Act of 1992. The 340B program (also known as the 602 program) was enacted to ensure that federal purchasers (i.e., Department of Veterans Affairs, Department of Defense, Public Health Service, and Coast Guard) were not at a disadvantage in negotiating discounts from pharmaceutical companies after Congress passed the Medicaid Rebate Program in 1990. The Medicaid Rebate Program established a mechanism for states to receive the "best price" for drugs for Medicaid recipients and the concern was that there was a disincentive for pharmaceutical manufacturers to negotiate discounts with other federal purchasers of drugs because those discounts would have to be passed along to state Medicaid programs through the formulas used to calculate "best price." The Veterans Health Care Act exempts prices negotiated by

The Cumberland County Medical Assistance Program (CCMAP)

CCMAP is a collaboration between the Cape Fear Valley Health System, Cumberland County Health Department and Department of Social Services, The CARE Clinic, and the Cumberland County Health Care Council. CCMAP assists eligible residents obtain free life-saving medications and works to enhance compliance and management of chronic diseases. It is supported by grants from The Duke Endowment, Kate B. Reynolds Charitable Trust, the NC Health and Wellness Trust Fund Commission, and donations from collaborating organizations. Low-income residents of Cumberland, Harnett, and Sampson Counties are eligible if they are on a stabilized dosage of medication, do not have insurance coverage for outpatient prescription drugs, do not qualify for government or third-party programs, and have incomes below 200% of the federal poverty guidelines. CCMAP began seeing patients in July 2002 and currently has 1,980 active patients with a waiting list of 575 applicants. CCMAP helps patients apply for the PAPs, dispenses some donated medications, and purchases other medications. CCMAP also provides prescription counseling to the patients. The average CCMAP patient receives about $1,800 in medications each year.

i The 340B program is administered by the Pharmacy Affairs Branch (PAB) of the Bureau of Primary Health Care (BPHC) in the Health Resources and Services Administration (HRSA) of the US Department of Health and Human Services.

certain other federal purchasers from being included in calculations for Medicaid best price. This Act was later expanded to include certain other health programs under section 340B of the Public Health Service Act.

Potentially eligible organizations include:[11]

- Community health centers,
- Federally qualified health center look-alikes,
- Migrant health centers,
- Health centers for public housing,
- Health centers for the homeless,
- School-based programs (Healthy Schools, Healthy Communities),
- AIDS clinics and AIDS Drug Assistance Program (ADAP programs),
- Hemophilia treatment centers,
- Black lung clinics,
- Certain disproportionate share hospitals, and
- Public health agencies can also obtain 340B drug discounts for medications dispensed in certain clinics, including family planning (Title X only), sexually transmitted diseases, and tuberculosis.

In the past, 340B drug discounts were limited to outpatient drugs, but the Medicare Modernization Act (2003) extended this provision to inpatient drugs at eligible public hospitals.[ii,12] Participating facilities receive an average savings of 25-50% off the average wholesale price (AWP) for covered drugs. Savings may be used to reduce the price of drugs for patients or to expand the healthcare facility's resources (e.g., increase revenue and allow them to treat more patients, offer more services, etc.). Many facilities adopt a sliding-fee scale that allows them to cover the entire medication cost for the neediest patients, pass the 340B savings on to some patients, and charge regular pharmacy prices to the highest income patients and those with good insurance coverage.[13]

The 340B program covers outpatient drugs that are prescribed for eligible patients of covered entities. Eligible "patients" are those who receive healthcare services from a covered entity. The patient is not eligible if medication services are the only services received from the covered entity (except for coverage of AIDS drugs through the AIDS Drug Assistance Program). Not all eligible organizations participate in the 340B drug discount program. For example, in 2003, only 13 of the 23 FQHCs in the state participated. Program requirements, including certain paperwork and accounting requirements, make it difficult for some organizations to participate.[iii]

The ORDRHD, Division of Public Health, NC Hospital Association, and NC Community Health Center Association are all working with potentially eligible safety net organizations to encourage them to participate in the 340B drug program, and have begun to see good results. Of the 56 rural hospitals nationally that were enrolled in the 340B program in the July 1, 2004 enrollment period, 16 were from North Carolina. More have enrolled since then. In addition to enrolling more of the potentially eligible organizations into the 340B drug discount program, the Task Force thought it would be important to amend the federal statute to make more organizations eligible to participate. Currently, safety net organizations including free clinics, Project Access models, or state-funded rural health clinics are ineligible to participate in the program. As a result, these organizations must pay much higher prices if they purchase medications for their low-income uninsured patients. To provide the same benefits to the

ii The Medicare Prescription Drug Bill exempts inpatient drugs purchased by 340B participating hospitals from manufacturers' best price calculations. Previously, the 340B Drug Pricing Program only related to outpatient drugs for disproportionate share (DSH) hospitals. Public Hospital Pharmacy Coalition. Opportunities for Pharmaceutical Manufacturers to Offer Deeper Discounts on Brand Name Inpatient Drugs for 340B Hospitals. National Association of Public Hospitals and Health Systems. Washington, DC: June 2004.

iii Drugs that will receive a Medicaid rebate cannot also be covered under the 340B Program discount because that would subject them to two layers of discounted prices. In order to prevent this from happening, covered entities that serve Medicaid patients must submit their Medicaid provider numbers during the registration process so that billing for drugs purchased through the 340B Program will not be included in the Medicaid rebate. Furthermore, eligible organizations that do not have in-house pharmacies can contract with community pharmacies. While contracts have helped many covered entities participate, they bring additional conditions that have to be met, including the development of tracking systems for the drugs that are purchased under the 340B Program and participation in audits to assure that drugs are being used for patients of the covered entity.

low-income uninsured patients of these organizations, the Task Force recommended that the NC Department of Health and Human Services, NC Community Health Center Association, and NC Free Clinic Association work with the NC Congressional delegation to amend the 340B statute so that other non-profit organizations with a mission to serve low-income uninsured patients can also obtain the benefits of this program. (see recommendation 7.1 in Chapter 7.)

Senior Care and Medicare Part D

Senior Care: NC Senior Care provides assistance in purchasing medications for certain low- and moderate-income seniors who are Medicare recipients. The program, which began in 2002, is funded by the Health and Wellness Trust Fund. It is being administered through the ORDHRD. Older adults (age 65 years or older) who are residents of North Carolina, with incomes below 250% of the federal poverty guidelines, are eligible for assistance with medications if they have no other source of prescription drug coverage. NC Senior Care works in conjunction with Community Care Rx, a Medicare-certified prescription drug discount plan. Together, eligible individuals are entitled to $1,200 per year in subsidies to help purchase medications and additional discounts on medications after the subsidy is exhausted. Seniors pay a copayment of 5% or 10% (depending on their income). This $1,200 per year subsidy is limited to older adults; it is not offered to people with disabilities who are also Medicare eligible (although the disabled may be eligible for a more limited subsidy of $600 per year through the Medicare prescription drug discount cards).

Medicare Part D: North Carolina Senior Care and the Community Care Rx drug discount cards are scheduled to end on December 31, 2005, immediately prior to the implementation of the new Medicare prescription drug program. Medicare Part D is scheduled to begin on January 1, 2006. It is voluntary among Medicare beneficiaries, but individuals who do not choose to participate when first eligible may be subject to a penalty (increased premium) if they later sign

Table 5.1
Medicare Part D Cost Sharing and Drug Coverage

Part D Coverage	Full Medicaid (dual enrollees)	<135% FPG	135-150% FPG	Above 150% FPG
Asset Test	No	$6,000/individual $9,000/couple	$10,000/individual $20,000/couple	No
Premium*	No	No	Sliding scale	~$35/month
Deductible*	No	No	$50	$250
Recipient costs for drug expenses up to $250	Covered	Covered	Covered	$250
Recipient costs for drug expenses between $250-$2,250 (preferred/ brand copay)	$1/$3 (<100%FPG) $2/$5 (above 100% FPG)	$2/$5	15% costs	25% costs
Recipient costs for drug expenses between $2,250-$5,100 (donut hole)	No gap, Part D pays all but copay above	No gap, Part D pays all but copay above	No gap, Part D pays all but copay above	100% of costs
Recipient costs for drug expenses over $5,100 (Catastrophic coverage)	No copay	No copay	$2/$5	Greater of 5% of $2/$5

** The premium and deductible level are indexed and will increase in future years.*

up for coverage. Individuals will be offered a choice of at least two prescription drug plans, e.g., Medicare Advantage plans (HMOs or PPOs) or stand-alone prescription drug plans (PDP).

Most individuals who participate in the new Medicare Part D program will have to pay a monthly premium and a $250 deductible (Table 5.1). Once the deductible is met, the prescription drug plan will pay 80% of the costs of covered medications until the person's drug expenses reach $2,250. At that point, Medicare Part D stops paying for prescription drug coverage until the person's drug expenses reach a "catastrophic" limit (currently $5,100). This is commonly referred to as the "donut hole," because Medicare pays nothing for drug expenses between $2,250 and $5,100. Medicare prescription drug plans will pay for all of the costs (minus certain allowable coinsurance or copay), once the individual's drug bill reaches the catastrophic threshold. In general, lower-income individuals (with incomes below 150% of the federal poverty guidelines) will have access to more complete coverage and lower cost-sharing than those with higher incomes. Once Medicare Part D is implemented, dual-eligible Medicaid recipients (i.e., those receiving both Medicaid and Medicare) will get their drug coverage exclusively through Medicare Part D.

Other State Programs

While there are some programs available to help low-income uninsured people obtain necessary medications and additional assistance available to low-income Medicare recipients, many low-income North Carolinians are still unable to obtain necessary medications. Other communities and states have developed innovative approaches to expand the availability of low-cost medications. The Task Force considered efforts of other states to expand the availability of low-cost prescription drugs, including: bulk purchasing programs, efforts to expand the availability of 340B drug discount programs or to obtain better drug prices for existing 340B eligible organizations, and programs that assist patients in purchasing lower cost medications from other countries.[14]

Bulk patient assistance program coordination efforts: In the bulk purchasing model of patient assistance programs, agreements are negotiated that allow an organization to screen for eligibility and get bulk product shipments, so neither the pharmaceutical company nor the provider has to deal with all of the applications. This is also advantageous because the bulk products are available when the patient is on-site, rather than requiring approval into the patient assistance program and for the medication to arrive by mail. Some bulk patient assistance program coordination efforts include:

- ***Health Kentucky:*** Health Kentucky is a nonprofit organization that has provided free healthcare to more than 250,000 patients since its inception in 1984. Eligibility for the program requires that an applicant is a Kentucky resident between the ages of 19-64 years; has no health insurance (including Medicaid, Medicare, Kentucky Children's Health Insurance Program, or Social Security Disability Insurance); and has an income level at or below federal poverty guidelines. As a part of Health Kentucky, members receive free covered medications under the Kentucky Pharmacy Providers Program. As many as 525 hospital and retail pharmacies donate their services to fill prescriptions for eligible patients at no cost. The medications themselves are donated by the following pharmaceutical companies: Abbott Laboratories, AstraZenca, Bristol-Myers Squibb, Eli Lilly and Company, Johnson & Johnson, Novo Nordisk Pharmaceuticals, Pfizer, and Pharmacia Corporation. Pharmacies get reimbursed by Anthem Prescription Management (APM) through a replenishment of the supply of dispensed medications.[15]

- ***Communicare (South Carolina):*** Communicare provides healthcare services to South Carolinians who have no other form of health insurance, including Medicaid, Medicare, and Veteran's benefits. Eligible participants have an income between 100% and 165% of the federal poverty guidelines and must be able to document one of the following conditions: currently employed, receiving unemployment compensation, receiving Social Security Retirement benefits, or receiving Social Security Disability benefits or Workman's Compensation. The Communicare benefits include the provision of a formulary of over 260 drugs, which are donated in bulk by pharmaceutical companies. Participating manufacturers include Abbott Laboratories, AstraZeneca, Bristol-Myers Squibb, Eli Lilly, GlaxoSmithKline, Johnson & Johnson, Pfizer, and TAP Pharmaceutical Products. The process works through a mail order facility, which sends 80% of the medications to physicians'

offices or clinics and 20% directly to patients' homes. Communicare partners with the South Carolina Free Clinic Association and provides 17 clinics with more than 135 different medications. Initially, Communicare patients received medications at no charge, but a $20 annual fee has recently been instituted. The program receives about $20 million worth of donated medications annually, and Pfizer drugs represent about 50% of those donations.[16,17]

- ***Georgia Partnership for Caring Foundation:*** The Georgia Partnership for Caring Foundation (GPCF) is a "private, non-profit organization comprised of healthcare providers who donate their time and products to provide non-emergency healthcare services for Georgia's low-income uninsured persons who are living below the federal poverty level." Residents of Georgia qualify for GPCF programs if they are uninsured and have a family income at or below 125% of the federal poverty guidelines. The prescription assistance program available through GPCF provides certain donated medications to participants free of charge. Medications are donated by Pfizer, Inc., Johnson & Johnson, Abbott Laboratories, and Novo Nordisk. Most participating pharmacies also waive their dispensing fees.[18]

- ***Virginia Rx Partnership:*** The Rx Partnership (RxP) in Virginia is increasing access to free medications for the uninsured by serving as a broker for the state in soliciting bulk medication donations from pharmaceutical companies and facilitating the distribution of those drugs to affiliate organizations. RxP licenses, credentials, and monitors affiliate pharmacies, which are typically operated by free clinics and community health centers. RxP negotiates with pharmaceutical companies for lower-cost and donated medications on behalf of these free clinics and community health centers. The program began working with 18 free clinics and four community health centers and, to date, is receiving medications from GlaxoSmithKline, Pfizer Pharmaceuticals, Wyeth Pharmaceuticals, and AstraZeneca.[19]

- ***Arkansas Health Care Access Foundation:*** The Arkansas Health Care Access Foundation (AHCAF) was established in 1989 as a volunteer-based medical referral program providing donated or low-cost medical care to low-income, medically-uninsured residents through a statewide network of volunteer medical professionals. Eligible residents have no other source of health insurance, including Medicare and Medicaid, and have an income below the Federal Poverty Guidelines. A statewide network of 345 pharmacies fills prescriptions at no charge to AHCAF patients. The medications are donated by Pfizer, GlaxoSmithKline, and Johnson & Johnson.[20]

The Task Force was very supportive of the effort to develop a bulk purchasing and centralized dispensing program and recommended that such a program be developed within the ORDRHD. The ORDRHD could help negotiate with the different pharmaceutical companies for bulk shipment of medications available through patient assistance programs. Participating safety net organizations, such as free clinics, medication assistance programs, and other non-profit safety net organizations, could determine eligibility for the PAPs. The medications could be shipped to a central warehouse and then redistributed to the participating safety net organizations to be distributed to the patients. This would enable safety net organizations to provide prescription counseling to their patients.

To accomplish this, the Task Force recommends that:

Rec. 5.3. North Carolina private foundations should consider three-year start-up funding at $180,000 per year to the NC Office of Research, Demonstrations and Rural Health Development to create a bulk medication replacement system.

Expanding the 340B Pricing Program or create larger purchasing alliances to obtain discounted prices: There have been some efforts to expand the use of 340B pricing. States are encouraging the creation of FQHCs, providing loans to health centers to start a pharmacy or partner with an existing community pharmacy, and encouraging referral relationships between organizations that allow them to make expanded use of 340B pricing. Some states have also created statewide bulk purchasing cooperatives that include 340B and/or non-340B entities. Some of these models include:

- ***Coordinated Care Network, (CCN), Pittsburgh, PA:*** CCN arranges for federally qualified healthcare centers to provide case management and pharmacy services to Medicaid patients in southwestern

Pennsylvania so they can access medications at 340B prices. CCN has "a central pharmacy and mail order facility that provides 340B [c]overed [e]ntities with on-site physician dispensing systems, prepackaged medications, and centralized refill, administrative, financial and regulatory reporting services."[21] CCN earns revenue from dispensing fees for its contracted pharmacy services. The program also provides 340B Poly-Pharmacy Member Case Management Services, which identify and provide persons with high pharmaceutical costs with case management services at a covered entity. Poly-pharmacy members are allowed to transfer prescriptions to the covered entity's 340B pharmacy (CCN), which provides them with free home delivery, refill reminders, and other services.[22]

- ***Safety Net Provider Purchasing Alliance (Alliance), California:*** The Alliance is a statewide bulk-purchasing cooperative that includes both 340B and non-340B entities. The Alliance leverages the purchasing power of community-based clinics, county clinics and hospitals, and academic medical institutions during negotiations with pharmaceutical manufacturers. In California, the program established a Pharmacy and Therapeutics Committee, which developed a preferred drug list for more competitive prices. The Alliance combines the 340B drug discount program with the Prime Vendor group purchasing organization to maximize cost-savings and has a two-tiered pricing structure to negotiate the best possible prices for both 340B and non-340B entities.[23]

- ***Texas Association of Community Health Centers:*** The Texas Association of Community Health Centers/ Cardinal Health offers a 340Better℠ pharmacy purchasing program, which provides sub-340B pricing on drugs to participating health centers through contracts with pharmaceutical manufacturers. The program targets high-cost, high-volume pharmaceuticals and uses the high-bulk purchasing needs of the participating health centers to negotiate very low pricing. The 340Better℠ is open to health centers throughout the United States, regardless of size or location.[24]

The Wake County Medical Society has tried to develop a system similar to the Coordinated Care Network of Pittsburgh to cover more low-income Medicaid and uninsured patients under the 340B drug discount program. The idea would be to extend WakeMed's 340B privileges to 29,000 Medicaid enrollees participating in Community Care of North Carolina (CCNC), as well as to other uninsured low-income people receiving care from primary care safety net clinics. The concept is to create a new corporation that includes all the safety net organizations in Wake County, including both 340B and non-340B organizations. The corporation would include WakeMed (a large 340B participating hospital), the Wake County Medical Society, Wake Health Services (an eligible 340B entity), Wake Human Services (which includes the health department), the Open Door Clinic (free clinic), and 30 private physicians' offices that participate in Community Care of North Carolina. Patients would receive case management services (e.g., disease management) through the Wake Community Care program under contract through Wake Med (a 340B entity). This would make all these patients eligible clients of a 340B participating organization. To accomplish this, Wake County would need to get a waiver from the Pharmacy Affairs Branch of the Bureau of Primary Health Care, within the US Health Resources and Services Administration, which administers the 340B program. This model should translate into lower medication costs for the Medicaid program, as well as the availability of deeply discounted medications for other safety net organizations. In addition, the program would help improve patient care by providing enhanced disease management and increasing the scope and nature of the drug utilization review process (DUR) to assess prescribed medications for appropriateness and potential drug interaction.

The Task Force was supportive of this effort as a means of extending 340B drug discount prices to additional safety net organizations. However, the project would require a separate agreement with the NC Division of Medical Assistance to cover Medicaid recipients under this initiative; the Division of Medical Assistance was unable to pursue this immediately because it is in the process of converting its Medicaid Management Information System (MMIS) to a new vendor (scheduled to be operational by January 1, 2006). Another complication recently emerged. The US Office of Pharmacy Services has become reluctant to grant waivers to expand the availability of 340B drug discount prices to other safety net organizations through coordinated networks. The Task Force is still supportive of pursuing these initiatives to extend

340B drug discount prices to additional safety net organizations, if the opportunity presents itself. Therefore, the Task Force recommends that:

Rec. 5.4. The NC Office of Research, Demonstrations and Rural Health Development should explore opportunities to expand 340B drug discount prices to low-income patients of other safety net organizations.

Programs to facilitate purchasing medications from other countries: Medications in Canada, Ireland, and the United Kingdom are, on average, between 25-50% lower than similar medications in the United States.[25] Currently, it is illegal to import medications from other countries. Despite the current prohibition on import of foreign drugs, some states have helped facilitate the purchase of lower-cost medications from these countries. Illinois, Wisconsin, and Missouri are currently supporting such a program; The I-Save-Rx program in Illinois has a contract to refill prescriptions with CanaRx, a Canadian pharmaceutical benefit manager. Participating patients must get the initial prescription filled in the US, but can get three-month supply refills from Canadian pharmacies. The participating pharmacies have been inspected by Illinois officials, and the program offers 100 of the most commonly prescribed brand name medications. However, the FDA issued letters of warning against CanaRx that their practices of importing prescription drugs from foreign countries are illegal, and that they could not provide the same assurances of drug safety as provided under the regulatory structure in the United States.[26,27] The Task Force decided not to pursue this option, given the current laws prohibiting foreign import of pharmaceuticals.

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