Task Force *for a* Healthier North Carolina

A Final Report on Findings and Recommendations on

Medicare Part D and Access to Prescription Drug Coverage for

North Carolina's Seniors

March 2007

Lieutenant Governor Beverly Perdue
Chair, Health and Wellness Trust Fund Commission

Task Force Co-Chairs

Senator Bill Purcell
Representative Verla Insko
Carole Bruce, HWTF Commissioner

University of North Carolina at Chapel Hill

Dr. Daniel Gitterman, Assistant Professor of Public Policy
Stephanie Coplin, Research Associate
Jessica Dorrance, Research Associate

Funding for UNC to support the Task Force is provided by the NC Health and Wellness Trust Fund

NORTH CAROLINA Health Wellness TRUST FUND

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

The Task Force respectfully submits the following recommendations on strategies to improve access to prescription drug coverage for North Carolina seniors.

Co-Chairs

Bill Purcell, North Carolina Senator, 25th District

Verla Insko, North Carolina Representative, 56th District

Carole Bruce, HWTF Commissioner**,** Attorney, Smith Moore LLP

Members

Bill Farmer, Vice President of Corporate Development, Time Warner Cable *(new member as of March 2007)*

Dr. Olson Huff, HWTF Commissioner

Dr. Jim Jones, Medical Director, Black River Health Services *(new member as of March 2007)*

H. Kel Landis III, Principal, Plexus Capital

Valeria Lee, President, Golden LEAF Foundation

Vernon Malone, North Carolina Senator, 14th District

Daniel McComas, North Carolina Representative, 19th District

Dr. Karen McNeil-Miller, President, Kate B. Reynolds Charitable Trust

Norma Mills, Lecturer, University of North Carolina, School of Government

Dr. Daniel Gitterman, Director (Ex Officio), Assistant Professor of Public Policy, UNC-CH

BACKGROUND

On November 16, 2006, Lieutenant Governor Beverly Perdue, Chair of the Health and Wellness Trust Fund Commission, announced the formation of the Task Force *for a* Healthier North Carolina. The Task Force was given the specific charge to hold public forums and make recommendations on strategies to improve access to health insurance coverage in North Carolina, including: access to prescription drug coverage for seniors; access to public health insurance for children; and access to health benefits for employees in small businesses. The Task Force for a Healthier North Carolina was created by a grant from the NC Health and Wellness Trust Fund Commission (HWTF). The Lewin Group was commissioned to prepare background policy briefings and to provide analytical support.[1]

The Task Force *for a* Healthier North Carolina sponsored two public meetings to explore strategies to improve access to prescription drug coverage for North Carolina's seniors. An initial public forum was held on November 16, 2006 in Chapel Hill, and an official Task Force meeting was held on December 13, 2006 in Raleigh. The Task Force invited formal presentations and written statements from the following individuals or organizations:

- **Rob Bizzell**, Owner, Realo Discount Drugs
- **Chris Bowen**, Pharmacist, Kerr Drug
- **Marlowe Foster**, Assistant Director, Government Relations and Public Affairs, Pfizer
- **Mark Gregory**, Vice President of Pharmacy, Kerr Drugs
- **James Hayes**, Citizen Advocate, HIV/AIDS Drug Assistance Programs
- **Becky Hunter**, Member, AARP Advocacy Council
- **Michael Keough**, Director, NC Rx, Office of Rural Health, Department of Health and Human Services
- **Dr. Ted Marmor**, Professor of Public Policy and Management, Yale University
- **Kevin Meriwether**, East Region Market President, Humana
- **Marjorie Morris**, Chief, Medicaid Eligibility Unit, Division of Medical Assistance, Department of Health and Human Services
- **Carla Obiol**, Deputy Commissioner, NC SHIIP, Department of Insurance
- **Phyllis Rogers**, Local Senior, Employee at Courtyard Marriott
- **Gary Salamido**, Director, State Government Affairs, GlaxoSmithKline
- **Alan Scantland**, Senior Vice President, Corporate Development, MemberHealth

- **Vandana Shah**, Policy Director, Health and Wellness Trust Fund Commission
- **Brian Shank**, Director, State Government Affairs, AstraZeneca
- **Steve Sherman**, AIDS Policy/ADAP Coordinator, Division of Public Health, Department of Health and Human Services
- **Gina Upchurch**, Executive Director, Senior PHARM*Assist*
- **Kathlyn Wee**, Director, State Public Affairs, UnitedHealthcare

Key findings from the Lewin Group's first background report to the Task Force, "The First Year for Seniors: Medicare Prescription Drug Coverage in North Carolina, 2006,"[2] are briefly summarized:

- Distribution of NC Medicare beneficiaries in 2006:
  - 32% (418,200) had retiree health insurance through an employer;
  - 29% (376,800) enrolled in a Medicare Part D plan;
  - 17% (230,000) were enrolled in both Medicare and Medicaid;[3]
  - 8% (102,300) had no "credible" coverage;[4,5]
  - 8% (109,600) were enrolled in a Medicare Part C plan;[6]
  - 6% (81,900) had some other form of "credible" coverage.

- Distribution of NC Part D beneficiaries by plan sponsor in 2006 (16 plans in total):
  - 27% (158,288): United-Pacificare
  - 21% (122,211): Humana
  - 10% (56,484): MemberHealth
  - 8% (44,735): Blue Cross Blue Shield North Carolina
  - 5% (29,538): WellCare
  - 5% (29,279): CIGNA
  - 24% (148,868): All other plans

- Medicare Part D beneficiaries in North Carolina will experience an average weighted premium increase of 7.8% in 2007.[7,8]

- Medicare Part D includes a low-income subsidy program (LIS) (known as "Extra Help"). As of June 2006, an estimated 91,700 North Carolinians are eligible but were not enrolled in the LIS program.[9,10]

- In 2006, seven PDP plans offered some coverage during the "doughnut hole" gap, but only Humana offered gap coverage for both generic and preferred brand-name drugs. In 2007, the total number of plans offering some gap coverage increased to fifteen; however, none of these plans offers coverage for preferred-brand drugs.[11]

For other key findings, see the full Lewin/HWTF/UNC-CH report at: http://www.healthwellnc.org/LewinPartD06report.pdf.

FINDINGS AND RECOMMENDATIONS

Finding 1: Improving Outreach and Enrollment for Federal "Extra Help" Low Income Subsidy (LIS) Premium Subsidies and NCRx

The Lewin Group reports that approximately 102,000 Medicare beneficiaries in North Carolina either do not have prescription drug coverage or do not have coverage that is as good as the standard Medicare benefit. In addition, as of July 2006, about 91,000 North Carolina seniors eligible for federal "Extra Help" had not enrolled in the program.[12] Finally, there are over 11,000 North Carolinians eligible for both Medicaid and Medicare who are expected to lose their automatic qualification for "Extra Help" for 2007.

In October 2006, Governor Easley announced NCRx, a premium assistance program to help lower-income seniors participate in the Medicare Part D prescription drug program.[13] NCRx offers an $18-per-month premium subsidy for eligible seniors. The Health and Wellness Trust Fund Commission (HWTF) approved $24 million in funding over three years (2007-09) to support the new program.[14] North Carolina seniors began applying for NCRx during the Medicare Part D enrollment period (November 15-December 31, 2006) and the premium assistance became available in January 2007.

NCRx is a qualified State Pharmaceutical Assistance Program (SPAP). SPAPs are state-funded programs that provide financial assistance for prescription drug coverage for low-income seniors and the disabled.[15] North Carolina's previous SPAP, Senior Care, ended in January 2006 when Medicare prescription drug coverage began. Prior to June 2006, HWTF invested $78 million to fund this prescription drug assistance program. Twenty-two states, including North Carolina, operate qualified SPAPs.[16] Of these, six (Delaware, Indiana, Nevada, Pennsylvania, North Carolina, and South Carolina) are supported in full or in part through tobacco settlement funds, and two (Massachusetts and Montana) are supported in part through a tobacco tax. The majority of SPAPs are funded through a mix of revenue and budget outlays including annual state allocations, lottery funds, casino taxes, fees, and general revenue.[17] Indiana's SPAP, known as HoosierRx, is the only other program that is fully funded by tobacco settlement funds.

With the implementation of the Medicare prescription drug benefit in 2006, SPAPs were provided with an opportunity to reevaluate their programs. Some states made the decision to terminate their SPAPs, while several states decided to wrap around the coverage provided by Medicare Part D and the low-income subsidies offered through the Medicare drug benefit. SPAPs have taken several approaches to fill the gaps in the Medicare drug benefit, including paying the premiums and cost-sharing requirements for members, covering the drugs that are not covered by Medicare Part D, and covering the "doughnut hole."

NCRx set forth the following eligibility criteria for its new program:

- North Carolina residency;
- Medicare beneficiary;
- age 65 or older;
- income at or below $17,150 for individuals and $23,100 for married couples (175% of the federal poverty level, FPL);

- combined savings, investments, and real estate (other than home, car, and $1,500 per person to cover burial expenses) of $20,000 or less for individuals and $30,000 or less for married couples;
- enrolled or will enroll in a Medicare Part D Prescription Drug Plan that participates with NCRx;
- no other prescription drug coverage that is as good as or better than Medicare Part D;
- not eligible for the full federal "Extra Help" subsidy for Medicare Part D.[18]

In addition to the premium assistance, enrolling in NCRx allows individuals to take advantage of a "special enrollment period" for Part D prescription drug plans. Ordinarily, once an individual enrolls in a Part D plan they are locked into it for a year, until the next enrollment/plan switching period (November 15-December 31). Enrolling in NCRx, however, allows individuals to enroll in or switch their Part D plan at the time of NCRx enrollment. This may be particularly beneficial for individuals who are eligible for but not enrolled in a prescription drug plan or for individuals in a plan that does not offer the best coverage for them (e.g., a plan in which the formulary has changed and no longer includes some or all of their medications).

Seniors enrolled in Medicare Part C/Medicare Advantage (Medicare plans that generally cover hospital, doctor, and prescription drug benefits all through one health plan) are excluded from participating in NCRx. However, 45.5% of Medicare Part C plan options in North Carolina charge an additional drug premium. Those individuals with Part C drug coverage pay an average of $26.36 per month in 2007.[19]

NCRx Enrollment Status and Outreach Activities

As of March 2007 and still very early in the enrollment process, NCRx had approved 3,849 applications. An additional 932 applications are being processed or are waiting for additional information. The enrollment period for NCRx was originally scheduled to coincide with the federal Part D enrollment period (November 15-December 31, 2006), but it has been extended without a formal deadline.

The majority of the NCRx budget is directed toward premium assistance for seniors. There is an administrative budget, about 9%, none of which is committed to outreach and enrollment activities per se. Within the current administrative budget for NCRx, funds for outreach and enrollment included a line item for printing and postage for a mailing to individuals, many of whom were enrolled in the Senior Care program. The Easley administration has set up a toll-free line, 1-888-488-NCRX (6279), and a Web site, www.ncrx.gov, so seniors can get information on NCRx and the Medicare plans.

The governor spent about $100,000 of leftover campaign money to air a television advertisement across the state announcing the prescription drug assistance plan for low-income senior citizens. The ad was aired as a free public service announcement in some areas. Governor Easley also distributed a radio ad to stations and asked them to air it as a free public service.[20] Posters announcing the program exist on the Web site.

On the Front Lines of Enrollment and Outreach Activities in North Carolina

North Carolina Seniors Health Insurance Information Program (SHIIP)
State Health Insurance Assistance Programs (SHIPs) provide personalized counseling and assistance to over 43 million Medicare beneficiaries and their caregivers nationwide who need help navigating the increasingly complex health care system, including the Medicare program. SHIPs are designed to provide accurate, understandable, and objective information, counseling, and assistance to Medicare beneficiaries on a wide range of health insurance issues, including Medicare, Medicaid, long-term care, and prescription drugs. While many local offices are located in Area Agencies on Aging, SHIPs also are located in other community-based organizations that serve older adults and people living with disabilities, such as senior centers and hospitals. Research has consistently found that Medicare beneficiaries prefer to receive information about Medicare through one-on-one assistance rather than through other means, such as written materials, mass media, or the Internet.

The Seniors Health Insurance Information Program (SHIIP) is North Carolina's lead state agency for answering questions and counseling Medicare beneficiaries and their caregivers about Medicare, Medicare Part D, and other health insurance concerns. SHIIP is a division of the Department of Insurance and has coordinators (both paid staff and volunteers) located in all 100 North Carolina counties. These coordinators help Medicare beneficiaries enroll in Part D plans, apply for the federal low-income subsidy (LIS), and respond to related questions and concerns.

Funding for SHIIP—which comes from both state and federal dollars—helps pay for the coordinators and helpline staff positions to assist with Medicare Part D enrollment. Historically, SHIPs have been funded by a growing, but inadequate amount of federal support that has been supplemented, in some instances, by state appropriations and local philanthropy. SHIP funding has historically been low: federal funding for the national network has remained relatively low and stable since the program began in 1991, when $10 million was allocated among the states in the form of grants. For the next 12 years, federal funding ranged from $10 million to $16 million per year. Following the enactment of the Medicare Modernization Act in December 2003, SHIP funding increased to $21.1 million in 2004 and $31.7 million in 2005. In 2006, funding decreased slightly to $30 million—about 70 cents per Medicare beneficiary.[21]

Prior to the implementation of the Medicare Modernization Act (MMA) and Medicare Part D, NC SHIIP received approximately $400,000 per year in federal funding. After the MMA, however, federal funding to all SHIPs was increased to assist with outreach and enrollment in Part D and with the general increased demand for services. In 2006, SHIIP in North Carolina received $871,625 in funding from the Centers for Medicare and Medicaid Services (CMS). The SHIIP office also received federal dollars from a one-time grant administered through the North Carolina Department of Health and Human Services in the amount of $444,088 to provide additional resources toward assistance with the transition to Medicare Part D. It is expected that the annual federal funding will eventually return to the original level (although it is not clear when this will happen), resulting in a decrease in funding of about $400,000 for North Carolina.

During the last enrollment period (November 15-December 31, 2006), SHIIP received 6,917 calls on their helpline. During the 2005 enrollment period, they received nearly twice as many

calls. In addition, they received close to 3,000 calls specifically related to NCRx. Over the course of a year from July 1, 2005 to June 30, 2006, they received over 80,000 calls.

Local Pharmacies
Pharmacies and pharmacists report being on the front lines of Medicare Part D. Many beneficiaries sought information about their prescriptions and their Part D plan directly from their pharmacist. One North Carolina pharmacist reported that customers often complain they do not receive helpful responses to enrollment and other questions from Part D plan hotlines. This is supported by a recent report from the Government Accountability Office (GAO) that documented the quality of service and information provided to Medicare beneficiaries by Prescription Drug Program (PDP) sponsor call centers. CMS requires each PDP to staff a toll-free call center that can provide information about the sponsor's plans. The report found that although calls were being answered quickly, the information provided was often not accurate or was incomplete. The GAO only obtained accurate and complete responses to their questions about one third of the time.[22]

Community-Based Organizations
In addition to SHIIP and pharmacies, a variety of community-based organizations play a role in providing information about Medicare Part D and assisting beneficiaries with navigating the doughnut hole. These agencies, which include senior centers, community centers, and other nonprofit agencies, reach out to individuals who may not be aware of other existing resources (such as SHIIP). Working with community-based organizations can be particularly effective because clients sometimes feel more comfortable receiving assistance from a provider they know and trust or from an agency they already visit for other services. In North Carolina, SHIIP operates "train-the-trainer" sessions every year throughout the state to educate and update providers who work with seniors about Medicare Part D and LIS enrollment.

Existing Models for Enrollment and Outreach Activities

Outreach and enrollment activities are critical to the success of any public program, and states have used several effective strategies to reach out to target populations for assistance programs. For example, many states have made significant investments in outreach and enrollment activities for their State Children's Health Insurance Programs (SCHIP). Some examples of successful outreach and enrollment strategies in SCHIP programs include: working with schools and other organizations and institutions already serving the target population; coordinating with community- and faith-based organizations; partnering with corporate sponsors; employing individuals as community outreach workers; funding monetary incentives to organizations; asking celebrities to promote the program; and advertising in the media. [23]

As previously mentioned, collaboration with community-based organizations can be very effective in cutting through consumer barriers. It can reduce stigma by associating the program with trusted organizations, increase awareness by providing information through trusted sources, facilitate the difficult application by providing assistance, and break down language and cultural barriers by engaging people through members of their own community.[24]

There is little experiential data on the success of specific outreach efforts related to SPAP premium assistance programs. There is literature, however, from related organizations outlining suggested outreach strategies. In 2005 and 2006, CMS provided guidance to SPAPs that received transitional grant funds. CMS recommended that SPAPs provide education via mailings, the Internet, public service announcements, and handbooks to Part D beneficiaries. CMS also recommended establishing a test population for future marketing strategies.[25]

The American Public Human Services Association (APHSA) referred to the states' role in Part D as "information intermediaries." While their recommendations are not specific to SPAPs, some of the same outreach efforts may translate to SPAP enrollment. The APHSA recommended public service announcements, posters, calendars, newspapers, interest group listservs, and mailings.[26]

Recommendation 1: Improving Outreach and Enrollment for Federal "Extra Help" Low Income Subsidy (LIS) Premium Subsidies and NCRx

The Task Force offers the following immediate recommendations to improve outreach and enrollment for Medicare Part D Extra Help and NCRx:

1.1 In order to meet the ongoing demand for enrollment, outreach, and Medicare Part D counseling, the SHIIP program will need consistent future funding. The Task Force supports reliable and sustainable federal as well as state funding to allow SHIIP to engage in strategic and long-term planning to meet the growing needs of the North Carolina Medicare population now and in the future. Through federal grants directed to state health insurance programs and with additional state funding to make up for any federal shortfall, SHIIP must have the resources to continue to provide free counseling and assistance via telephone and face-to-face interactive sessions, public education presentations and programs, and media activities.

1.2 The Task Force recommends committing resources (potentially from within the existing NCRx administrative or program budget) toward additional community-based outreach and enrollment efforts. For example, small mini-grants ($2500 to $5000) could be made available to community-based organizations that serve seniors in an effort to assist with both the NCRx and Medicare Part D open enrollment period. Currently, there are more than 20 organizations comprising the Medicare Partners State-Level Coordinating Committee, a group of public and private entities with an interest in ensuring that as many North Carolinians as possible enroll in a Part D plan and that low-income people sign up for the subsidy program. A subcommittee of the Medicare Partners State-Level Coordinating Committee, which would include the Seniors Health Insurance Information Program (SHIIP) director, the NCRx director, a HWTF senior staff member, and two members of the senior community-based organizations community, could serve to solicit, award, and monitor innovative community-based NCRx outreach and enrollment grants.

1.3 The Task Force recommends targeting additional resources from the existing NCRx (administrative) budget to those counties with the greatest under-enrollment in "Extra

Help" as well as those counties that operate with volunteer rather than paid SHIIP staff coordinators.

1.4 The Task Force recommends that SHIIP outreach coordinators collaborate with local retail and independent pharmacies to provide outreach and enrollment assistance and activities within dispensing pharmacies. Many Medicare Part D beneficiaries request information directly from their pharmacist, which makes the pharmacy an appropriate setting for targeted enrollment and outreach efforts. For example, Kerr Drug, a retail pharmacy chain in the Carolinas, operates "Health Care Centers" in several of their store locations, offering some clinical services and basic counseling on insurance-related issues. By placing SHIIP volunteers in these and other existing in-house settings, the pharmacy can become a one-stop location for many seniors who are in need of additional assistance. For example, SHIIP staff or volunteers could make use of the Benefits Checkup, a Web-based decision support tool that helps beneficiaries and those who serve them, understand and assess their current situation before enrolling in an appropriate Medicare Prescription Drug plan. At the pharmacy counter, Benefits Checkup can be used to help determine if seniors qualify for Medicare's Extra Help or other prescription savings programs and allow them to apply for many of these programs on line.

1.5 The Task Force recommends that NCRx pilot an online application process during the next federal Medicare Part D (2008) open enrollment period and evaluate its impact on program enrollment. In other states, electronic applications have been shown to increase program enrollment. SHIIP coordinators and volunteers, as well as some community-based organizations, currently provide Web-based assistance for seniors who are enrolling directly in Medicare Part D (see Medicare Drug Plan Finder, http://www.medicare.gov). Evaluations of electronic application procedures conclude that:

- applying online is quicker (the time between application submission and eligibility determination is reduced compared to paper applications);
- there is increased consumer satisfaction;
- application errors are reduced because applicants are required to complete all necessary information before proceeding to the next screen or are prompted when data is missing;
- because information is collected electronically, the process may improve an agency's ability to efficiently access data.

Some online application systems have "application assisters" who can work with beneficiaries to input data. This could be a particularly useful feature for seniors who may not be familiar with Web-based applications.

Finding 2: Strengthening NCRx

The $18-per-month premium assistance available through NCRx is an important step toward helping low-income seniors gain access to affordable prescription drug coverage. As previously mentioned, enrolling in NCRx also allows beneficiaries to take advantage of a special enrollment

period for Part D plans. For those who are eligible, the benefit amount offered by NCRx is sufficient to cover the full premium cost of the least expensive PDP offered in North Carolina in 2007 ($17.80). This financial assistance is critical for seniors who are not eligible for the federal LIS but may not be able to afford the cost of a prescription drug plan on their own. This least expensive plan, however, carries with it a $265 deductible that individuals are expected to pay out of pocket before their benefits begin.

In order to be eligible for this premium assistance, individuals must meet the eligibility criteria mentioned in the previous section. These include income requirements as well as an asset test. While the asset test for NCRx eligibility is relatively simple for the applicant, asset tests by nature penalize savings and discourage low-income individuals from building wealth. Requiring an asset test also adds staff time and contributes to the overall administrative costs of operating a program.[27] In addition, NCRx benefits are only available to seniors. This excludes an entire segment of the Medicare population—those under 65 years of age who are disabled and receive Social Security Disability Insurance (SSDI).

Recommendation 2: Strengthening NCRx

The Task Force encourages state policy makers to monitor enrollment trends during the first year of NCRx program operation. The following recommendations for the second year of the program are contingent upon availability of funds on January 1, 2008:

Strengthening NCRx Benefit Design

2.1 For new Medicare Part D enrollees, the current $18 monthly premium assistance available through NCRx provides financial support to cover the full premium cost ($17.80) for only the least expensive Prescription Drug Plan (PDP) in North Carolina, which carries a $265 annual deductible. If funding is available, the Task Force recommends consideration of an increase in premium assistance ($7.30-per-member-per-month increase in 2007) to cover the full premium cost of the least expensive plan that does not carry a $265 deductible ($25.30 per month in 2007).

2.2 Currently, the NCRx program pays premium assistance directly to the Part D plan on behalf on the beneficiary. For those seniors already enrolled in a Part D plan, participation in NCRx requires a senior to stop automatic deduction of their Part D premium from their social security checks. The Part D plan charges those who have selected a higher-premium plan for the difference between the monthly plan premium and the state's $18 premium contribution. The Task Force recommends consideration of additional benefit designs, including the offering of a "debit card," in addition to the direct premium payment options. The state would contribute a fixed annual amount to a senior's prescription drug spending account, equal to the current premium assistance amount (i.e., $18 per month x 12). This benefit would operate similar to the current "flexible health spending account" debit cards that are available to state employees through a contract with AON consulting. Seniors could use the card to pay coinsurance, co-pays, or other costs at the pharmacy counter.

Expanding NCRx Eligibility

If funding is available in year 2, the Task Force recommends the following:

2.3 Consider eliminating the asset test, (currently set at $20,000 for individuals and $30,000 for married couples) which could boost enrollment and reduce overall administrative costs.

2.4 Consider expanding the eligibility threshold from 175% FPL (federal poverty line) to 200% FPL ($19,600 for individuals and $26,400 for married couples).

2.5 Consider expanding NCRx to cover all Medicare Part D beneficiaries under 200% FPL, including eligible Social Security Disability Income (SSDI) beneficiaries under age 65.

Finding 3: Navigating the Gaps in Part D Coverage

The doughnut hole is the gap in Medicare Part D coverage during which the beneficiary is responsible for 100% of their prescription drug costs. Once the beneficiary reaches the initial coverage limit of $2,400, coverage stops completely and they must spend $3,850 in true out-of-pocket expenses (TrOOP) before Medicare Part D catastrophic coverage begins.

The Role of the Health and Wellness Trust Fund

Over the last four years, the Health and Wellness Trust Fund has taken several significant steps to provide a safety net for seniors and other low income populations. Recognizing that Senior Care, HWTF's former statewide prescription drug program for low-income seniors, was not a complete solution to the problems that North Carolina seniors and low-income individuals under 65 were facing, HWTF created a network of Medication Assistance Programs (MAP) to serve the underserved populations without access to prescription drugs. Since 2003, HWTF has provided over $17 million in funding to MAP grantees to help seniors and other low-income individuals identify and apply for the lowest-cost prescription drugs available through public and private programs, including Patient Assistance Programs and discount card programs offered by pharmaceutical companies. In order to simplify the application process, HWTF equipped each grantee with computers and custom-design software (MARP) that had been developed by the NC Office of Research, Demonstrations and Rural Health Development (ORDRHD).

In addition to helping beneficiaries locate free or low-cost prescriptions, many MAP grantees also contract with local pharmacists to counsel seniors in identifying drug utilization issues such as drug-to-drug interactions and duplicative therapies. MAP grantee sites provided over $68.8 million worth of free medications to nearly 40,000 patients from January 2003 to December 2005, representing a 6:1 return on HWTF's grant investment. More than 8,000 of these patients also received medication management (MM) services during this period. Because of their leadership in the medication access field, MAP grantees have also stepped in to provide critical assistance to seniors facing the doughnut hole.

The Role of Patient Assistance Programs (PAPs)

Patient Assistance Programs (PAPs), often sponsored by pharmaceutical companies, provide free or low-cost prescription drugs to people with limited finances. Each company develops its own program structure and eligibility criteria. They only offer assistance with medication produced by their own company (for example, Pfizer's PAP only offers assistance with Pfizer products). At the Task Force public meeting, representatives from three of the leaders in patient assistance—Astra Zeneca, GlaxoSmithKline, Pfizer—presented information on their respective programs. Each includes some assistance for individuals with Medicare Part D. The details are briefly described below.

- AstraZeneca
  Prescription assistance is available to Part D beneficiaries through AstraZeneca's "AZ Medicine and Me" program. Enrollees will pay no more than $25 for a typical 30-day supply of AstraZeneca medicines. This program has no enrollment fee and is available at most local pharmacies. To be eligible, individuals must have an annual income below $30,000 (couples must earn less than $40,000 per year), must be taking a listed AstraZeneca product, and must have spent at least 3% of their annual household income on prescription drugs during the current year.[28]

- GlaxoSmithKline
  Prescriptions are available to Part D beneficiaries through GSK's Access program. To be eligible, individuals must have an income below 250% FPL, live in one of the 50 states or District of Columbia, and provide proof that they already have spent $600 on outpatient medicines in the current calendar year. Oncology patients who are enrolled in Part D plans will be able to receive their medicines through GSK's existing Commitment to Access patient assistance program by meeting the following criteria: income below 350% FPL, residence in one of the 50 states or District of Columbia, and proof that the patient has already spent $600 on outpatient medicines in the current calendar year.[29]

- Pzifer
  Pfizer's PAP, known as Connection to Care, is aimed primarily at those without any form of insurance or prescription drug coverage; however, Part D beneficiaries can apply for a "Hardship Exemption" in order to qualify for assistance. To be eligible, individuals must have an income below 200% FPL and the patient and the patient's physician must complete and sign the application form. Hardship exemption requests are reviewed on a case-by-case basis. If approved, the patient will receive their approved Pfizer medicines at no charge. The 90-day supply of medicine is shipped to the physician's office for pickup by the patient.[30]

These three companies are considered leaders in patient assistance programs. Many other pharmaceutical companies do not offer PAPs or offer only very limited assistance to individuals with insurance coverage. PAPs also may restrict which drugs are covered in their program. For instance, they may not include assistance toward medications for certain illnesses, such as cancer and HIV/AIDS. Finally, prescription medications provided through PAPs do not count toward a Medicare beneficiary's true out-of-pocket costs (TrOOP). See Appendix A for a full listing of

companies that offer patient assistance to Part D beneficiaries and Appendix B for additional information about PAPs and the TrOOP.

Recommendation 3: Navigating the Gaps in Part D Coverage

The Task Force offers the following strategies to continue helping seniors navigate the gaps in Medicare Part D coverage:

3.1 The Task Force recommends that SHIIP and other community-based outreach organizations continue to encourage seniors with significant prescription drug needs to enroll in a Part D plan that offers some doughnut hole coverage. Currently, the least expensive Part D plan premium for coverage during the gap is $42.90. Although the coverage only applies to generic prescriptions, this would ensure that seniors receive some financial assistance for approved medications.

3.2 If the NCRx premium assistance is increased to $25.30 (or to the cost of the least expensive Part D plan with no deductible in 2007), the state, in promoting the expanded benefit, would contribute more than 50% of the cost of the least expensive plan that offers doughnut hole coverage ($42.90 in 2007).

3.3 The HWTF MAP grantees should continue outreach efforts to assist those seniors affected by the doughnut hole. Additionally, the pharmacists providing medication therapy management (MTM) services available through the new NCRx Care initiative (described further in recommendation 4) should coordinate with MAP grantee organizations and refer those seniors facing the doughnut hole to additional assistance in locating free or low-cost medications.

3.4 GlaxoSmithKline, AstraZeneca, and Pfizer, leaders in offering Patient Assistance Programs (PAPs), are all members of the Pharmaceutical Research and Manufacturers of America (PhRMA). The Task Force encourages GlaxoSmithKline, as a North Carolina-based company, to work with state leaders to showcase the important role of the private sector in providing prescription drug assistance for low-income Medicare Part D beneficiaries facing the doughnut hole**.**

Finding 4: The Design of NCRx Care and Managing Out-of-Pocket Drug Costs

In October 2006, the Health and Wellness Trust Fund Commission announced NCRx Care, a medication therapy management (MTM) program.[31] Building upon its Medication Assistance Program (MAP), established in 2002, the Office of Rural Health, through an agreement with HWTF, will contract with retail and community pharmacists to provide MTM services, which include counseling Medicare enrollees on the most appropriate and cost-effective use of their federal drug coverage benefit, helping monitor health status, and identifying potentially harmful drug-to-drug interactions. The HWTF has approved $2 million over three years to compensate

pharmacists who counsel eligible seniors. The Office of Rural Health is currently soliciting public bids for the administration of NCRx Care.

By providing multiple services, MTM has been viewed as an effective method for helping save lives and reduce overall healthcare costs.[32] This type of service can be crucial for seniors and those with chronic illnesses, who often must take multiple medications.

MTM Under Medicare Part D

Currently, under the federal Medicare Part D benefit, the Centers for Medicare and Medicaid Services define MTM-eligible individuals as those who:

- have multiple chronic diseases, such as, but not limited to, diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure;
- are taking multiple covered Part D drugs; AND
- are identified as likely to incur annual costs for covered Part D drugs that exceed the level specified by the Secretary of Health and Human Services.

CMS set a $4,000 threshold of annual costs that PDPs are to use for identifying targeted beneficiaries eligible for MTM services; this amount was published on the Medicare.gov Web site in a document for plan sponsors submitting a bid to become a PDP. Further clarification by CMS staff notes that the $4,000 takes into account all true-out-of-pocket spending for covered Part D drugs. The statutory language notes that MTM services may be provided by a pharmacist or other qualified provider.[33]

Large MTM programs from Medicare Part D plans like Humana and Blue Cross Blue Shield do not typically deviate from the aforementioned federal guidelines. Humana's MTM program, for example, requires that patients have at least two chronic illnesses, take five or more systemic medications, and expect to spend more than $4,000. The MTM program offered through Blue Cross Blue Shield of North Carolina requires that eligible Medicare beneficiaries meet the following criteria: 1) they must suffer from at least five chronic diseases, with at least two of the following: hypertension, high cholesterol, congestive heart failure, diabetes, or asthma; 2) they must have claims for at least six different covered PDP medications within a 12-month period or less; 3) they are likely to incur annual costs of at least $4,000 for PDP-covered medications.[34]

Other organizations, including the American Pharmacists Association (APhA), have developed a more comprehensive definition of what constitutes MTM. Some key components, according to AphA, are:

- performing or obtaining necessary assessments of the patient's health status;
- formulating a medication treatment plan;
- selecting, initiating, modifying, or administering medication therapy;
- monitoring and evaluating the patient's response to therapy, including safety and effectiveness;
- performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events;

- documenting the care delivered and communicating essential information to the patient's other primary care providers;
- providing verbal education and training designed to enhance patient understanding and appropriate use of medications;
- providing information, support services, and resources designed to enhance patient adherence to therapeutic regimens;
- coordinating and integrating medication therapy management services within the broader health care management services being provided to the patient.[35]

MTM Services in North Carolina

Efforts to offer MTM services in North Carolina have already been implemented and can provide insights for the design of NCRx Care. Four examples of existing MTM programs include:

- Senior PHARM*Assist*
  Senior PHARM*Assist* works closely with participants' healthcare and social service providers to ensure the best pharmaceutical care possible. Seniors enrolled in the prescription card program are seen every six months for recertification and medication therapy management. A pharmacist works one on one with each senior to review every medication (prescription, over-the-counter, and herbal) that he or she is taking. The pharmacist also assesses whether a participant can properly perform any tasks associated with taking those medications (i.e., drawing up insulin, using an inhaler, or administering eye drops). Finally, the pharmacist discusses health promotion strategies with the patient and makes referrals to other relevant programs, such as medical transportation, home-delivered meals, and senior centers. After 24 months in the program, the rate of participants reporting any hospitalizations decreased by 51%**,** and the rate of participants reporting any emergency department visits declined by 27%**.**

- AlaMAP
  Alamance Medication Assistance Program (AlaMAP) has provided MTM services for more than five years. Since the inception of Medicare Part D, the AlaMAP MTM program has focused primarily on seniors; most clients are referred to the program through their physician or through local agencies. AlaMAP received a one-time MAP grant from the HWTF, and most of the MTM services continue to be grant funded. The program is looking into the possibility of charging small sliding-scale fees for these services in the future. Some of its many accomplishments include documented declines in emergency room visits and more appropriate medication regimens for participants. Like some other MTM programs across the state, AlaMAP tracks clients, services provided, and client outcomes in a database. AlaMAP also has dispensed more than $7 million in PAP medications since July 2001.

- North Carolina Department of Health and Human Services, Division of Medical Assistance (DMA)
  DMA reimburses pharmacists who provide medication management assistance to Medicaid patients across the state. It is important to note that DMA's program is not a medication therapy management program as defined by CMS and does not provide some

of the key MTM components as defined by the APhA MTM working group. When a Medicaid patient reaches 12 prescriptions, they are offered the services by the pharmacist. During the first six months, the pharmacist requests that the patient transfer all the prescriptions to one pharmacy, there is a consultation between the pharmacist and the patient's physicians, and the pharmacist reviews medication utilization with the patient. The goal at the end of the six-month review is to do one or more of the following: reduce the overall number of medications taken, change the dosage or type of medications taken to increase effectiveness or decrease unfavorable interactions, and reduce the total medical costs incurred by the patient. In return for these services, DMA pays the pharmacist $10 per enrollee per month. The $10 figure was reached through actuarial estimates. Quality control for this program is limited. A section within DMA regularly audits a portion of the pharmacists' billings for the services. A section chief reported that there have been a few cases in which DMA has had to reclaim overpaid monies. At some point, DMA would like to measure the patients' overall health care spending as a determinant of success for the program. The program began in June 2006, and many of the details, including quality control, are still being established.[36]

- University of North Carolina, School of Pharmacy Medication Management Program for Older Adults
  This program, which is part of the UNC School of Pharmacy, provides MTM services to seniors living in Orange County, North Carolina. Individuals aged 60 years and older can join by contacting the program directly. The first visit usually takes approximately one hour, and follow-up visits are based on the individual's needs. The pharmacist obtains consent from the senior to review his or her medical record and to discuss the medication evaluation and recommendations with his or her physician. The pharmacist works with the physician to optimize medication therapy and provides the individual with a written summary of the medication evaluation. The pharmacist documents all medication evaluations and recommendations and shares the records with the physician and other health care providers. In addition, one of the UNC clinical pharmacists currently provides MTM and other education services to patients at Chapel Hill Internal Medicine (CHIM). The pharmacist works one day a week at CHIM and sees patients of all ages who are in need of MTM-type services. Patients can request these services on their own or be referred by their physician at CHIM.

As the NCRx Care program begins designing its benefits, lessons from these types of programs can be used to create a new program that best meets the needs of seniors and other Medicare Part D beneficiaries.

Vendors to Manage MTM

The HWTF, through the Office of Rural Health, is currently soliciting bids for the administration of NCRx Care. A number of private companies have designed innovative systems for MTM. One of the leading vendors in administering MTM services is Outcomes Pharmaceutical Care.

Outcomes is a privately held limited liability company that administers MTM services. With Outcomes, pharmacists can document and be reimbursed for MTM services via the Web. As of

October 2006, four Medicare Part D plans had contracted with the administrator of this program to provide MTM services. The company has been working with employer groups, health plans, union funds, Medicaid, and others since 1999. Using such services provides the conveniences of a standardized reporting mechanism, data-collection efforts, and quality-control parameters.[37] Once a year, patients may receive a "comprehensive medication review" in which a pharmacist meets face to face with the patient for a full consultation. If in the same year, the patient experiences a circumstance that warrants an additional review (hospitalization, changes in medication, etc.), the individual pharmacist retains the autonomy to make that decision. For each consultation, the pharmacist submits a claim to Outcomes for $50. Additional claims may apply if the pharmacist must complete follow-up action, such as contacting the patient's physician. Outcomes pay the pharmacist in one of two ways depending upon the preference of the contracting program: 1) through a fee-for-service operation in which they bill the organization monthly for pharmacy claims or 2) the contracting organization's payment of a specific amount per member per month.

Outcomes monitors service quality by utilizing an outside committee that reviews pharmacist claims and ensures that the appropriate actions were taken, and that the billed amount was equal to the services rendered.

Recommendation 4: The Design of NCRx Care and Managing Out-of-Pocket Drug Costs

The Task Force views NCRx Care and appropriate brown-bag counseling by dispensing and non-dispensing clinical pharmacists as an important additional benefit offered as a companion program to NCRx.

The Task Force offers the following recommendations to aid in the design of NCRx Care and to help seniors manage out-of-pocket drug costs:

4.1 As one of the first steps in designing the new assistance program, NCRx Care will need to establish "eligibility" criteria for its beneficiaries. The program should use the NCRx criteria as a base and build in additional eligibility requirements specific to those most in need of MTM services. NCRx Care would become an added benefit to the NCRx $18 monthly premium assistance. In addition to those who are eligible for NCRx, NCRx Care should consider offering the benefit to all Medicare beneficiaries who receive the federal low-income subsidy (also known as "Extra Help").

4.2 The Task Force recommends that NCRx Care use the definition and standards of MTM provided by the APhA (American Pharmacists Association) as a guide for designing the services to be provided. This would ensure that beneficiaries receive comprehensive medication management services that include monitoring health status, providing one-on-one counseling, collaborating with physicians, and documenting action and health outcomes. At a minimum, NCRx Care should use the eligibility guidelines provided by the Centers for Medicare and Medicaid Services (CMS) for MTM.

4.3 The Task Force recommends that NCRx Care make dispensing and non-dispensing (for example, community based pharmacists) pharmacists eligible for reimbursement.

4.4 The Task Force recommends that NCRx Care take active and immediate outreach and enrollment steps to begin educating beneficiaries as well as pharmacists about the available services and how they might participate in the program.

Finding 5: Improving the Coordination of Health Care Delivery for Seniors

Several Task Force members and advocates for seniors expressed concern that low- to moderate-income Medicare beneficiaries must navigate a confusing network of prescription drug plans, health care and other service providers, and other public programs. There is a growing need for community-based organizations that can meet a variety of needs and challenges for seniors.

There are organizations currently providing this kind of coordination. For example, Senior PHARM*Assist*, a nonprofit organization in Durham, NC, promotes healthier living for Durham seniors by helping them obtain and better manage needed medications and by providing health education**,** community referral**,** and advocacy. In most cases, Senior PHARM*Assist* provides tailored, hands-on assistance for seniors and younger Medicare beneficiaries (people with disabilities) including help finding a Medicare prescription drug plan that works best for them, applying for the low-income subsidy, medication management services, and help locating other resources such as transportation assistance and home-delivered meal services. Through its prescription drug card program, Senior PHARM*Assist* also acts as a secondary payer. This helps participants meet their deductibles and cost-sharing related to Medicare drug plans.

In addition to these types of organizations, North Carolina has a rich history of developing community-based health care systems, and the Task Force expressed particular interest in initiatives that create community-care networks for seniors, similar to the infrastructure of the Community Care of North Carolina Program (CCNC).

For example, the physicians who participate in CCNC felt the need to encourage providers to take an informed look at their prescribing habits for their Medicaid patients. They felt the need to evaluate the relative costs of medicines prescribed in key therapeutic categories. They identified the top 100 drugs by Medicaid expenditures in North Carolina and then arranged those compounds in a tiered fashion by average wholesale price (AWP), where Tier 1 drugs offer the greatest potential cost savings to the Medicaid program. The tiered list is shared with providers throughout the CCNC network via posters, pocket-sized reference cards, and an electronic drug reference entitled ePocrates. As a result of this voluntary, provider-driven effort, preliminary findings show the post-rollout period of February 2003-March 2003 had 22% lower expenditures compared to a pre-rollout period of September 2002-October 2002. The actual savings equals approximately $640,000.[38]

Additionally, the CCNC infrastructure has allowed the state to develop and implement a nursing home polypharmacy initiative that creates pharmacist and physician teams to review drug profiles and medical records for Medicaid patients in nursing homes. They determine if a drug

therapy problem exists and then recommend a change and perform follow-up. Approximately 9,208 nursing home residents used more than 18 drugs within a 90-day period. The criteria used to identify individuals for the initiative included: inappropriate drugs for the elderly known as "Beers drugs"; drugs used beyond usual time limit; drug use warnings and precautions; the prescription advantage list; and potential therapeutic duplication. Of the 9,208 patients, recommendations were made on 8,559 of them and 74% or 6,359 had recommendations implemented. This initiative has proven that the pharmacist-and-physician team approach reduces costs and improves quality of care.

In 2005, the North Carolina General Assembly passed legislation to expand the scope of the CCNC managed care network to include aged, blind, and disabled populations. Implementation has recently begun. North Carolina has also applied for a Medicare Redesign Demonstration Waiver that would allow for a joint agreement between CMS and the North Carolina Community Care Network (a nonprofit organization that represents all the CCNC networks) to help manage recipients dually eligible for both Medicare and Medicaid.

A NC Pilot for Collaboration and Coordination of Care

Another example of coordinated care efforts is the Program of All-Inclusive Care for the Elderly (PACE), a unique, capitated managed care benefit for the frail elderly that seeks to provide better care and cost savings by integrating preventive, acute, and long-term care into one package. For most participants, the program provides needed services through an adult day care center to enable them to live at home, rather than in a nursing home or other institution. This coordinated-care model began as a federally supported demonstration project but, as part of the Balanced Budget Act of 1997 (BBA), PACE was made a permanent provider under Medicare and a state option under Medicaid. PACE features an integrated financing system through both Medicare and Medicaid.

There are nearly 40 PACE programs in 19 states that are serving approximately 17,000 Medicare and Medicaid beneficiaries. PACE serves individuals who are age 55 or older, certified by their state to need nursing home care, able to live safely in the community at the time of enrollment and live in a PACE service area. Although all PACE participants must be certified to need nursing home care, only about 7% nationally reside in a nursing home. If a PACE enrollee does need nursing home care, the program pays for it and continues to coordinate the enrollee's care. By delivering all needed medical and supportive services, PACE is able to provide the entire continuum of care and services to seniors with chronic-care needs while maintaining their independence in their homes for as long as possible. Care and services include:

- adult day care that offers nursing, physical, occupational and recreational therapies, meals, nutritional counseling, social work, and personal care;
- medical care provided by a PACE physician familiar with the history, needs, and preferences of each participant;
- home health care and personal care;
- all necessary prescription drugs;
- social services;
- medical specialists such as audiology, dentistry, optometry, podiatry, and speech therapy;

- respite care;
- hospital and nursing home care when necessary.

In 2004, the North Carolina General Assembly passed legislation to develop two pilot PACE programs (see Appendix C). One is being developed by Elderhaus, a daytime care facility for seniors based in Wilmington, NC. The second is being developed by Piedmont Health Services, which operates six community health centers throughout the state. This second pilot program has received some start-up funding through CMS as part of a new initiative to develop PACE programs in rural areas.

Creating a new PACE program is an in-depth process that requires the completion of an extensive provider application, access to start-up funds, and development of the infrastructure needed to provide services. A prospective PACE-sponsoring organization must work with state and federal agencies, internal and external funding sources, community organizations, and health care providers to assemble an operational program. PACE provider applications are submitted to the state Division of Medical Assistance (DMA) before being passed to the Centers for Medicare and Medicaid Services for final approval. The approval process typically requires twelve months. In North Carolina, the two programs are in the process of creating the PACE infrastructure and completing applications. They are tentatively scheduled to be operational by fall 2007 (Elderhaus) and summer 2008 (Piedmont Health Services).

Although the PACE designation as a permanent provider allowed for rapid expansion nationwide, growth has been slower than expected. Some recent research has presented explanations for possible barriers to expansion. These include issues of competition between PACE programs and other state-sponsored programs for the same population, poor understanding of the program, and a lack of financing.

With funding from the Centers for Medicare and Medicaid Services, Mathematica Policy Research is evaluating the PACE program. Its evaluation is estimating the program's impact on beneficiaries in their first through fourth years of enrollment, as well as trying to understand how the program has changed now that it is a permanent component of the Medicare program. In particular, the evaluation is answering these four questions:

- What are the effects of PACE on quality of care, as measured by mortality, self-reported health, and physical functioning of enrollees after their first full year of enrollment?
- How do Medicare and Medicaid outlays for PACE enrollees compare with outlays that would have been made in the absence of the PACE program?
- How did the Balanced Budget Act, which made PACE a permanent part of the Medicare program, affect PACE operations?
- How well does a community-based physician model operate in two current PACE sites and at a non-PACE site that serves a similar population?

The analysis includes two parts based on different data sources. A study of the effects on quality of care relies on a telephone and in-person survey of Medicare beneficiaries who entered PACE and home- and-community-based waiver programs in seven states between 2001 and 2003. A study of the effects on Medicare and Medicaid expenditures analyzes a cohort who entered

PACE in 1999, using Medicare and Medicaid claims supplemented by data from PACE sites on hospital and nursing home utilization by enrollees.

Recommendation 5: Improving the Coordination of Health Care Delivery for Seniors

5.1 The Task Force encourages continued exploration of whether the PACE program is an effective model for coordinated care for seniors. The Task Force believes that the results of a pending federal evaluation as well as further monitoring of the two pilot sites in North Carolina could provide policy makers with valuable information on models to coordinate care for the state's most vulnerable seniors. For example, policy makers might want to support a future evaluation of how the community-based physician model operates in the current pilot PACE sites and at a non-PACE site that serves a similar population.

Other Strategies to Access Prescription Drug Assistance in NC

While beyond the scope of the Task Force's formal charge, the Task Force acknowledges two important additional programs for accessing prescription drugs. These federally funded programs—340B pricing and the Aids Drug Assistance Program (ADAP)—provide assistance for low-income seniors as well as low-income individuals under age 65.

340B

340B pricing refers to a federal designation given to facilities that serve very low-income individuals. States offer discounts through the 340B drug pricing program, which requires pharmaceutical manufacturers participating in Medicaid to offer drug discounts to federal and state-supported facilities that serve the most vulnerable populations. Receiving lower-cost medications through one of North Carolina's qualified facilities is likely much more affordable for those with very low incomes than purchasing a Medicare Part D prescription drug plan. As of July 2006, 309 facilities in North Carolina had 340B discount status.[39]

Covered facilities include nonprofit disproportionate-share hospitals owned by or under contract with state or local governments; federally qualified health centers (FQHCs); AIDS Drug Assistance Programs (ADAPs); Ryan White CARE Act Title I, Title II, and Title III programs; and clinics for tuberculosis, black lung, family planning, sexually transmitted diseases, hemophilia, public housing, homeless, urban Indian and native Hawaiian populations.[40]

Aids Drug Assistance Programs (ADAPs)

The North Carolina AIDS Drug Assistance Program (ADAP), also know as the HIV Medications Program, uses a combination of state and federal funds to provide low-income residents with assistance in obtaining essential, life-sustaining medications to fight HIV/AIDS and the opportunistic infections that often accompany the disease. The program purchases the medications in bulk from a pharmaceutical wholesaler, and a central pharmacy dispenses and sends the prescriptions for each client. There is no cost to the individual covered under this

program for the drugs that are on the program's formulary. The individual is responsible for the cost of other drugs that they receive that are not covered by the program.

Individuals living with HIV/AIDS typically have extremely high prescription drug costs and many of the necessary medications do not have a generic equivalent. For those with HIV/AIDS who have prescription drug coverage through Medicare Part D as SSDI recipients, North Carolina ADAP has paid the cost of the drugs while in the doughnut hole. Similar to prescription drugs available through PAPs, these medications do not count toward the true-out-of-pocket costs that Medicare beneficiaries must pay in order to qualify for catastrophic coverage.

Further exploration of a range of community-based outreach and enrollment strategies as well as additional state assistance to address some of the gaps in the Medicare Part D benefit remain critically important to ensure access to affordable prescription drug coverage for all of North Carolina's seniors.

Conclusion

Many of the problems Medicare beneficiaries face stem from larger, systemic issues that no single authority can fully address. The Task Force would like to recognize the impact that programmatic complexity has on individual beneficiaries, and urges leaders at the state and federal level to push for a more user-friendly version of the Part D program and the health care system for seniors in general. We believe that less complexity and more coordination will lead to better health care and therefore, better health outcomes for all Medicare beneficiaries. Further, we hope that the recommendations put forth by this document will help to make North Carolinians' experience with Medicare better, and contribute to the overall discussion of reform.

Appendix A

Patient Assistance Program Eligibility Criteria and Medicare Part D

Will your Medicare patients be eligible for Patient Assistance Programs?
Updates are made as they are received. Last updated March 21, 2007.

No Medicare Patients may apply for PAPs		
Actelion	**Dermik**	**Salix**
American Regent	**Eisai**	**Savient**
Axcan	**IVAX**	**Sciele Pharma**
Biogen	**MedImmune**	**Scios**
Boehringer Ingleheim	**Millenium**	**Teva/Gate**
Cangene	**Mylan**	**Watson**
Celgene	**PDL Biopharm**	
Cephalon	**Purdue**	
Medicare Patients without a Part D plan may apply for PAPs		
Alpharma	**Endo**	**Novo-Nordisk**
Amgen (Part D see below)	**Enzon**	**Ortho-Biotech** (Part D see below)
Amylin	**ESP**	**Reckett Benckiser**
Astellas Pharma (Part D see below)	**Forest**	**Reliant**
	Galderma	**Roche** (Part D see below)
Bayer	**Genentech**	**Serono**
Berlex	**Genzyme** (Part D see below)	**Shire** (Part D see below)
Biovail	**Graceway**	**Solvay**
Bradley Pharmaceuticals	**Intermune**	**TAP** (Part D see below)
Centocor	**King**	**UCB**
Daiichi Sankyo	**MedPointe**	**Upsher-Smith**
Duramed	**MGI**	**Valeant** (Part D see below)
Eli Lilly (Part D see below)	**NitroMed**	**Vistakon**
All Medicare Patients may apply for PAPs		
Abbott *	**Digestive Care**	**Novartis**
Alcon (Part D enrollees must submit a hardship letter)	**Eytech**	**Pfizer*** (Some medications may not be available to Part D enrollees)
	Gilead*	**Procter & Gamble** (Cannot be LIS eligible)
Allergan*	**GlaxoSmithKline—**Part D enrollees use GSK Access program	**Sanofi-Aventis** (Appeal process for financially needed patients who have a life threatening condition confirmed by physician)
AstraZeneca—Part D enrollees use AZ Medicines & Me	**Johnson & Johnson***	
	Kos	
Bristol Myer Squibb* Berlex/Beta Seron Fnd. (Cannot be LIS eligible)	**Merck***	**Schering-Plough**
	Merck/Schering Plough *	**Takeda***
	NABI (Cannot be LIS eligible)	

Chiron/TOBI—Part D enrollees may be eligible for product or co-pay assistance		**Wyeth** (Part D enrollees must submit a hardship letter or LIS denial letter)
Medicare Part D patients may apply for selected medications		
Amgen—Sensipar and Enbrel only **Astellas Pharma—**Prograf only **Eli Lilly—**Zyprexa, Forteo and Humatrope only	**Genzyme—**Renagel only through Renagel Part D PAP **Ligand—**only if drugs not in patient's Part D plan **Ortho-Biotech—**Only if drugs not in patient's Part D plan **Roche—**Only if drugs not in patient's Part D plan	**Shire—**Fosrenol, only if drug not in patient's Part D plan **TAP—**Prevacid Only **Valeant—**Only if drugs not in patient's Part D plan; Part D enrollees ineligible for Infergen PAP

LIS = Low-Income Subsidy within Part D

*Will consider consider allowing some Part D enrollees to apply for PAPs; contact the company for more information.

Appendix B

Patient Assistance Programs (PAPs)

What are patient assistance programs?
Patient assistance programs (PAPs) are programs set up by drug companies that offer free or low-cost drugs to individuals who are unable to pay for their medication. These programs may also be called indigent drug programs, charitable drug programs, or medication assistance programs. Most of the best known and most prescribed drugs are included. All of the major drug companies have patient assistance programs, although every company has different eligibility and application requirements. Companies offer these programs voluntarily; the government does not require them to provide free medicine.

How do patient assistance programs work?
The patient applies for the drug company program that has the needed medicine. Information on medication available through patient assistance programs and the company programs offering these drugs may be found on the RxAssist.org Web site. Many application forms are available and can be filled out online or printed out. Some companies' programs require that a physician or heath care advocate (someone working in a physician's office or in a clinic) get the form by calling the program. Many times in these cases, the patient assistance program will screen for eligibility before sending the form. The form that is sent will have a patient-specific identification number on it. After it is filled out and submitted, the drug company will decide whether the patient is eligible to receive the medication for free. If the patient is eligible, the medication may be sent to the patient's home, the physician's office, or a local pharmacy, depending on the program. Some, but not all companies send letters informing patients and/or physicians about whether the patient has been approved for their patient assistance program.

What are the eligibility requirements for patient assistance programs?
Eligibility varies program by program. Generally, individuals must have incomes under 200% of the federal poverty level (below $25,660 for a family of two people), cannot have prescription coverage from any public or private source, and must be a U.S. resident or citizen. Some companies require that the patient have no health insurance.

For a list of program decisions regarding Medicare and patient assistance program eligibility, see http://www.rxassist.org/docs/medicare-and-paps.cfm.

PAPs and True-Out-of-Pocket Expenses (TrOOP)
The monetary value of free or low-cost drugs provided through PAPs cannot be counted toward an individual's true-out-of-pocket expenses (TrOOP). TrOOP costs are the expenses that count toward the annual Medicare drug plan threshold (also known as the doughnut hole) of $3,850 (in 2007) for the year.

Information adapted from: http://www.rxassist.org/faqs/default.cfm#3 and http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2006/AdvOpn06-03F.pdf

Although many pharmaceutical companies operate PAPs, they face one main barrier to providing assistance to Part D beneficiaries—the federal anti-kickback statute. When companies offer people free or reduced cost medications or financial assistance toward particular prescription drugs, these actions may be viewed as inducements toward the purchase of specific drugs from specific companies as well as rewarding businesses reimbursable by a federal health care program. The following rules currently guide the actions of PAPs:

Prohibited:

- Cannot "offer, pay, solicit, or receive any remuneration to induce or reward the referral or generation of business reimbursable by any federal health care program."
- Assistance that has a monetary value cannot be counted toward an individual's true-out-of-pocket costs (TrOOP), the expenses that count toward the annual Medicare drug plan threshold (also known as the doughnut hole) of $3,850 (in 2007) for the year.

Permissible:

- Pharmaceutical manufacturers may make cash donations to independent charities that provide financial assistance to Part D beneficiaries.
- PAPs may elect to provide free drugs to financially needy Medicare Part D enrollees outside the Part D benefit.
- Pharmaceutical manufacturers may be able to join together in a collaborative PAP if safeguards are put in place to avoid steering and kickback issues as illustrated by the Office of Inspector General.

Appendix C

PACE

The Program of All-Inclusive Care for the Elderly (PACE) is a capitated benefit authorized by the Balanced Budget Act of 1997 (BBA) that features a comprehensive service delivery system and integrated Medicare and Medicaid financing. The program is modeled on the system of acute and long-term care services developed by On Lok Senior Health Services in San Francisco, California. The model was tested through CMS (then HCFA) demonstration projects that began in the mid-1980s. The PACE model was developed to address the needs of long-term care clients, providers, and payers. For most participants, the comprehensive service package permits them to continue living at home while receiving services rather than be institutionalized. Capitated financing allows providers to deliver all services that participants need rather than be limited to those reimbursable under the Medicare and Medicaid fee-for-service systems.

The BBA established the PACE model of care as a permanent entity within the Medicare program and enables states to provide PACE services to Medicaid beneficiaries as a state option. The state plan must include PACE as an optional Medicaid benefit before the state and the Secretary of the Department of Health and Human Services (DHHS) can enter into program agreements with PACE providers.

Participants must be at least 55 years old, live in the PACE service area, and be certified as eligible for nursing home care by the appropriate state agency. The PACE program becomes the sole source of services for Medicare-and Medicaid-eligible enrollees.

An interdisciplinary team consisting of professional and paraprofessional staff assesses participants' needs, develops care plans, and delivers all services (including acute care services and, when necessary, nursing facility services), which are integrated for a seamless provision of total care. PACE programs provide social and medical services primarily in an adult day health center, supplemented by in-home and referral services in accordance with the participant's needs. The PACE service package must include all Medicare- and Medicaid-covered services, and other services determined necessary by the interdisciplinary team for the care of the participant. PACE providers receive monthly Medicare and Medicaid capitation payments for each eligible enrollee. Medicare-eligible participants who are not eligible for Medicaid pay monthly premiums equal to the Medicaid capitation amount, but no deductibles, coinsurance, or other type of Medicare or Medicaid cost-sharing applies. PACE providers assume full financial risk for participants' care without limits on amount, duration, or scope of services.[41]

PACE PILOT PROGRAM FUNDS FROM HOUSE BILL 1414 (2004)

SECTION 10.12.(a) The Department of Health and Human Services, Division of Medical Assistance, shall develop a pilot program to implement the Program for All-Inclusive Care for the Elderly (PACE). One pilot site shall be planned for the southeastern area of the state and the other pilot site shall be planned for the western area of the state. The division shall design the pilot program to access federal Medicaid and Medicare dollars to provide acute and long-term care services for older patients through the use of interdisciplinary teams. When implemented,

services provided through the PACE pilot program may include physician visits, drugs, rehabilitation services, personal care services, hospitalization, and nursing home care. The PACE pilot program may also offer social services intervention, case management, respite care, or extended home care nursing.

SECTION 10.12.(b) Of the funds appropriated to the Department of Health and Human Services, Division of Medical Assistance, for the 2004-2005 fiscal year, the sum of one hundred twenty-three thousand one hundred fifty-six dollars ($123,156) shall be used to support two positions in the Division of Medical Assistance to develop the pilot programs in accordance with subsection (a) of this section. These funds may also be used to contract for actuarial analysis as part of the development of the pilot programs.

SECTION 10.12.(c) The Department of Health and Human Services shall report to the House of Representatives Appropriations Subcommittee on Health and Human Services and the Senate Appropriations Committee on Health and Human Services on March 1, 2005, on PACE pilot program development. The report shall include services proposed to be offered under the pilot program, administrative structure of the pilot program, number of Medicare and Medicaid eligible recipients anticipated to receive services from the PACE pilot sites, and the projected savings to the state from PACE pilot program implementation.

SECTION 10.12.(d) Nothing in this section obligates the General Assembly to appropriate funds to implement the PACE program statewide.

[1] http://www.unc.edu/news/archives/nov06/taskforcegitterman111606.htm.
[2] The Lewin Group. "The First Year for Seniors: Medicare Prescription Drug Coverage in North Carolina, 2006." 15 November 2006. *North Carolina Health and Wellness Trust Fund* <http://www.healthwellnc.com/LewinPartD06report.pdf> (accessed December 2006).
[3] These individuals are also known as dual eligibles and they were automatically enrolled into a Medicare Part D plan. Full-benefit dual eligibles qualify for the low-income subsidy and therefore, pay no premiums or deductibles and have copayments usually ranging from about $1.00 to just over $3.00. This population is not subject to the doughnut hole.
[4] "Medicare Factsheet: The Medicare Prescription Drug Benefit." November 2006. *The Kaiser Family Foundation.* <http://www.kff.org/medicare/upload/7044-05.pdf> (accessed December 2006).
[5] Credible coverage is defined as coverage that is at least as good as the standard Medicare drug benefit. Individuals that do not enroll in Medicare Part D once they become eligible and have not had credible coverage prior to enrolling face a penalty equal to 1% of the national average monthly premium for each month they delay enrollment.
[6] The Medicare Part D benefit is offered through two types of private plans: stand-alone PDPs for people who receive other Medicare benefits through the fee-for-service program, and Medicare Advantage plans (MA-PDs, also known as Medicare Part C), such as HMOs or PPOs, that cover drugs and other Medicare benefits.
[7] The Lewin Group. "The First Year for Seniors: Medicare Prescription Drug Coverage in North Carolina, 2006." 15 November 2006. *North Carolina Health and Wellness Trust Fund.* <http://www.healthwellnc.com/LewinPartD06report.pdf> (accessed December 2006).
[8] This average is weighted by 2006 PDP enrollment and thus excludes three PDPs that were offered in 2006 but were not offered as the same plans in 2007. Together, these three plans have 5,470 in total enrollment for 2006.
[9] "Medicare Factsheet: Low-Income Assistance Under the Medicare Drug Benefit." May 2006. *The Kaiser Family Foundation.* <http://www.kff.org/medicare/upload/7327.pdf> (accessed December 2006).
[10] The LIS is substantial premium and cost-sharing subsidies for Medicare beneficiaries with low incomes and modest resources. These subsidies are intended to reduce or eliminate enrollees' out-of-pocket expenses associated with the drug benefit, including premiums, deductibles, copayments, and costs in the coverage gap (doughnut hole).
[11] Some PDPs offer additional coverage for medications (either generics only or preferred and generic drugs) during the doughnut hole. These plans usually require a higher monthly premium.
The Lewin Group. "The First Year for Seniors: Medicare Prescription Drug Coverage in North Carolina, 2006." 15 November 2006. *North Carolina Health and Wellness Trust Fund.* <http://www.healthwellnc.com/LewinPartD06report.pdf> (accessed December 2006).
[13] "Gov. Easley Outlines Prescription Drug Assistance for Seniors: *'North Carolina Rx' Will Help Provide Low-income Elderly the Medications They Need."* 18 October 2006. *North Carolina Office of The Governor.* <http://www.governor.state.nc.us/News_FullStory.asp> (accessed December 2006).
[14] "Gov. Easley Outlines Prescription Drug Assistance for Seniors: *'North Carolina Rx' Will Help Provide Low-income Elderly the Medications They Need*." 18 October 2006. *North Carolina Office of The Governor.* <http://www.governor.state.nc.us/News_FullStory.asp> (accessed December 2006).
[15] "State Pharmaceutical Assistance Programs." 1 August 2006. *US Department of Health and Human Services, Centers for Medicare and Medicaid.* <http://www.cms.hhs.gov/States/07_SPAPs.asp> (accessed December 2006).
[16] "State Pharmaceutical Assistance Programs in 2006-07: Helping to Make Medicare Part D Easier and More Affordable." 10 January 2007. *National Conference of State Legislatures.* <http://www.ncsl.org/programs/health/SPAPCoordination.htm> (accessed December 2006).
[17] "State Pharmaceutical Assistance Programs in 2006-07: Helping to Make Medicare Part D Easier and More Affordable." 10 January 2007. *National Conference of State Legislatures.* <http://www.ncsl.org/programs/health/SPAPCoordination.htm> (accessed December 2006).
[18] The federal "Extra Help" benefit offers assistance to Medicare beneficiaries up to 150% of the federal poverty level (FPL) ($14,700 for individuals and $19,800 for married couples) who pass the asset test of $10,000 for individuals and $20,000 for married couples. NCRx offers assistance to seniors (age 65+) up to 175% FPL ($17,500/individuals and $23,100/married couples) and increases the asset limits to $20,000 for individuals and $30,000 for married couples.
[19] "Landscape of Local Plans State-by-State Breakdown." 5 January 2007. *US Department of Health and Human Services.* < http://www.medicare.gov/medicarereform/local-plans-2007.asp#NC> (accessed December 2006).
[20] http://www.newsobserver.com/659/story/525234.html.

[21] Health Assistance Partnership, "State Health Insurance Assistance Programs: A Critical Resource for Medicare Benefiaries." May, 2006. <http://www.hapnetwork.org/assets/pdfs/HAP-SHIP-Issue-Brief-2006-Final-May-2006.pdf>.
[22] United States. Government Accountability Office. "Medicare Part D: Prescription Drug Plan Sponsor Call Center Responses Were Prompt, but Not Consistently Accurate and Complete." June 2006. <http://www.gao.gov/new.items/d06710.pdf> (accessed December 2006).
[23] "State Children's Health Insurance Program (SCHIP): Outreach and Enrollment." *National Conference of State Legislatures.* January 2000. <http://www.ncsl.org/programs/health/outenrol.htm>.
[24] "Recommendations for Creating a Sustainable Approach to Healthy Start Plus® Outreach in Franklin County." A report to Access Health Columbus. *Children's Defense Fund-Ohio*. November 2001. <http://www.cdfohio.org/publications_research/pub_library/access_health/pdfs/access_health_cols.pdf>.
[25] http://www.cms.hhs.gov/States/Downloads/SPAPGrantGuidance.pdf.
[26] http://cwd.aphsa.org/confs_calls_events/docs/Gale-Arden.pdf.
[27] Summer, Laura, and Lee Thompson. "How Asset Tests Block Low-Income Medicare Beneficiaries from Needed Benefits." May 2004. *The Alliance for Health Reform.* <http://www.allhealth.org/briefingmaterials/HowAssettestsblocklow-incomebeneficiaries-310.pdf> (accessed December 2006).
[28] "AZ Medicine & Me™ for People in Medicare Part D Program." *AstraZeneca.* http://www.astrazeneca-us.com/content/patientAssistance/astrazeneca-medicine-and-me.asp.
[29] "GlaxoSmithKline Announces New Patient Assistance Programs for Low-Income Medicare Part D Patients." GlaxoSmithKline. <http://www.bridgestoaccess.com/pdfs/PressRelease12072006.pdf> (accessed December 2006).
[30]"Pharmaceutical Assistance Program Drug Details." *US Department of Health and Human Services.* <http://www.medicare.gov/pap/drugdetails.asp?drug_id=13987&drug_name=Ogen>.
[31] "Lt. Governor Perdue Announces a Unique Senior Drug Program to Save Money and Lives." 13 October 2006. North Carolina Health and Wellness Trust Fund. <http://www.healthwellnc.com/hwtfc/pdffiles/PressNCRxCare-10-13-06.pdf>.
[32] The Lewin Group. "Medication Therapy Management Services: A Critical Review; Executive Summary Report." May 17, 2005. *American College of Clinical Pharmacy*. <http://www.accp.com/position/mtms.pdf> (accessed December 2006).
[33] "A Summary of Medication Therapy Management Programs in the Medicare Modernization Act and the Center for Medicare and Medicaid Services' Implementing Regulations." April 2005. *American Society of Health-System Pharmacists.* <http://pharmacy.rutgers.edu/725/584/MTM%20Reading.pdf> (accessed December 2006). Federal guidance on MTM can be found online at United States. Department of Health and Human Services. Centers for Medicare and Medicaid Services. "Medicare Program; Medicare Prescription Drug Benefit." 28 January 2005. <http://a257.g.akamaitech.net/7/257/2422/01jan20051800/edocket.access.gpo.gov/2005/pdf/05-1321.pdf> (accessed December 2006).
[34] "Medicare Prescription—Quality Assurance Policies and Procedures." 29 September 2006. *Blue Cross Blue Shield of North Carolina.* 23 February 2007. <http://www.bcbsnc.com/plans/medicareprescription/quality-assurance.cfm#medtherapy>.
[35] Medication Therapy Management Services Definition and Program Criteria. APha MTM Working Group. July 2004.
[36] Interview. January 12, 2007. Thomas D'Andrea, RPH, MBA, Section Chief, Pharmacy and Ancillary Services, NC DHHS, Division of Medical Assistance.
[37] Jeffrey Brewer, Pharm.D., BCPS; Patty Kumbera. "Establishing a Web-based Program for Reimbursement for Medication Therapy Management Services." *American Journal Health-System Pharmacists* 63 (19) (2006): 1806-1809. Posted 10.31.2006. Found online at www.medscape.com/viewarticle/545490.
[38] "Evaluating Coordination of Care in Medicaid: Improving Quality and Clinical Outcomes." Prepared Witness Testimony, Mr. Jeffrey Simms, Assistant Director, North Carolina Division of Medical Assistance. <http://energycommerce.house.gov/reparchives/108/Hearings/10152003hearing1111/Simms1739.htm>.
[39] "States and the 340B Drug Pricing Program" 4 January 2007. *National Conference of State Legislatures*. <http://www.ncsl.org/programs/health/drug340b.htm>.
[40] "Discount Drug Pricing Program Eligibility." 2004. *US Dept. of Health and Human Services, Pharmacy Services Support Center.* <http://pssc.aphanet.org/about/whoiseligible.htm>.

[41] Overview of "The Program of All-Inclusive Care for the Elderly (PACE)." *Centers for Medicare and Medicaid Services.* <http://www.cms.hhs.gov/pace/>.