

WHITE PAPER ON ACCESS TO PRESCRIPTION DRUG SERVICES

I. Issue Background

A. Access to Prescription Drugs

Heart disease, cancer, and stroke are among the leading causes of death in the United States and Pinellas County (Florida Department of Health 2006). Typically, death from these diseases and disorders arises from chronic conditions that develop over an extended period of time, often after prolonged exposure to one or more risk factors. Chronic conditions place an increased demand on the health care delivery system, particularly when they manifest in multiple fashion within specific populations (e.g., uninsured, minority, and others who are at-risk for health disparities). Chronic conditions contribute substantially to racial and ethnic disparities in health status -- particularly for African Americans (Reed and Hargraves 2003) -- and are among the principal reasons why blacks die at younger ages and at higher rates than their white peers. Individuals with chronic conditions require on-going and often medically complex treatment regimens, including the extended use of prescription drugs. Successful health outcomes are heavily dependent on effective medical management and the delivery of comprehensive and consistent treatment therapies.

Access to prescription drugs is a critical element in the effective management of chronic disease. Health care consumers who are low-income, uninsured and/or medically under-served are often forced to choose between the use of prescription drugs and the purchase of other essential goods and services, such as food and housing (Duncan et al. 2005). In general, the cost of prescription drugs is a specific barrier to care for low-income working-age adults, particularly African Americans and Latinos who report being substantially less likely to fill prescriptions than their white peers (Reed and Hargraves 2003). However, the inability to purchase prescription drugs is an issue that transcends race and ethnicity among working age adults, 28.3% of uninsured and 7.6% of insured Americans report needing medicines but not being able to afford them (Lasser et al. 2006). The inability to purchase and utilize prescription drugs often exacerbates chronic conditions, and ultimately results in acute episodes that require hospitalization and/or urgent and more costly care in a hospital emergency room (Duncan et al. 2005). In 2003, 64% of the U.S. community population had an outpatient drug expense and the average person had ten prescriptions filled. Prescription medications accounted for \$177.7 billion (20%) of health care costs. Patients were responsible for 45% of those prescription drug costs through out of pocket charges (Stagnitti 2006).

1. Hillsborough and Pinellas County

In Pinellas County 9.9% of residents earn incomes below 100% of the Federal Poverty Level (FPL) and 27.0% are below 200% FPL. In Hillsborough County 12.5% of residents earn incomes below 100% FPL and 30.1% are below 200% FPL. Guidelines define 100% and 200% of the Federal Poverty Level as an annual income between \$9,800 and \$19,600 for individuals and \$20,000 to \$40,000 for families of 4. While this segment of the community is able to manage day-to-day expenses like buying food and maintaining cars, research indicates that they have insufficient resources to protect

against unexpected medical bills, and they almost never have sufficient funds to purchase health insurance on their own in today's market (Duncan et al. 2005).

A recent report indicated that in Florida the agricultural industry represents the single largest component of uninsured adults (50%), followed by adults employed in construction (42%), other services (37%), leisure and hospitality (35%), professional and business services (27%) and wholesale/retail trade (23%) (Nissan et al. 2006). In 2003 an estimated 195,237 individuals were employed in those top six at-risk occupations in Pinellas County and 277,139 in Hillsborough County (United States Census).

The self-reported uninsured rate for adults earning less than \$25,000 annually was 33.8% in Pinellas County and 29.5% in Hillsborough County, compared to a state rate of 31.6%. The self-reported uninsured rate for adults earning between \$25,000 and \$50,000 annually was 17.2% for both counties (Florida Department of Health 2006). The per capita income was \$28,125 annually in Pinellas and \$26,016 in Hillsborough (United States Census 2006).

B. Medicare Part D - Doughnut Hole

Under Part D of Medicare, standard enrollees will pay the first \$250 of their medications (in 2006). After this initial deductible, 75% of their drug costs will be covered, leaving the enrollee to pay 25%. However, once the total medication costs have exceeded \$2,250 (in 2006), the enrollee must pay for the drugs completely out of pocket, while still paying a monthly premium. This gap in coverage is known as the doughnut hole. Individuals who exceed \$5,100 in drug costs (in 2006) will trigger catastrophic coverage which will cover 95% of drug costs (Cruz and Hickey 2006).

According to conservative estimates of the Kaiser Family Foundation, it is predicted that out of 11.8 million Medicare enrollees whose plans include a coverage gap, nearly seven million will hit the doughnut hole. The doughnut hole will actually grow and increase over time. In future years the deductible increases by \$25 yearly and the catastrophic coverage threshold increases to \$5,596 in 2007 and \$6,158 in 2008 (Cruz and Hickey 2006).

The average Medicare enrollee's total drug spending for 2006 is estimated to be \$3,081. Accordingly, that enrollee would fall into the doughnut hole by September 22, 2006 (Cruz and Hickey 2006).

Enrollees with chronic health conditions such as heart disease, mental illness, diabetes, and AIDS or life threatening illnesses such as cancer are at added risk of hitting the doughnut hole. The American Cancer Society stated that cancer patients who take expensive drugs such as Gleevec and Tarceva, which cost \$2,500 a month, will be affected. Likewise the National Multiple Sclerosis Society points out that their clients, whose drugs cost \$1,300 to \$2,000 a month, reach the gap quickly (Wolf 2006).

II. MedNet[®]

In 1999, the Pasco-Pinellas District Health Plan concluded that residents die most often from heart disease, cancer, stroke, Diabetes and lung disease and that these chronic conditions contribute substantially to racial and ethnic health disparities.

Individuals with chronic conditions required ongoing and often medically complex treatment regimens, including extended use of prescription drugs. Access to prescription medications was identified as a critical element in the effective management of chronic disease, yet the high cost of medications is a barrier to care that requires individuals to choose between purchasing prescription drugs or other essential goods and services.

Community leaders recommended developing a Compassionate Drug Patient Assistance Program to expand access to prescription drugs for low-income uninsured adults, including seniors. In 2000 Pinellas County Government funded a compassionate drug program and retained the Suncoast Health Council to design and implement program services.

MedNet[®] assists individuals in acquiring prescription medications from pharmaceutical companies that offer patient assistance programs. The program utilizes a unique database which provides the instructions and applications needed to request medications from 90 pharmaceutical companies offering prescription coverage for over 1,000 medications. Currently MedNet[®] is operating seven programs from six sites in Pinellas County: Bayfront Family Health Center, Suncoast Health Council (which rotates staff to community sites and the Mobile Medical Van), St. Petersburg Free Clinic (2), Community Health Center of Clearwater, Johnnie Ruth Clarke Health Center, and Turley Family Health Center.

MedNet[®] enhances the community's capacity to manage chronic disease by facilitating timely and consistent access to prescription drug therapy. MedNet[®] eliminates economic and literacy barriers that impede access to prescription drugs by securing free medications for low-literate, low-income uninsured adults, including the working poor. MedNet[®] also promotes collaboration between private physicians, their patients, the safety net system, and the pharmaceutical manufacturing industry, which is required by law to provide pharmaceutical support to chronically-ill adults with limited income. The application process used by manufacturers requires applicants to be literate, mentally focused, and extremely resourceful however, and these are challenging skills for multiply-diagnosed individuals to master. MedNet[®] clears those obstacles by working one-on-one with patients to assist them with the application and refill process.

Between 2000 and 2005, the MedNet[®] program secured over \$2 million in free medications with a return on investment of \$6.67 for every \$1 spent to provide program services. In the most recent five month period (March - September 2006), 541 clients received medications valued at \$278,342.

The tables on the following page provide a breakdown of the demographics, class of drugs secured, and insurance status of those served.

**Value of Medications Secured by Class
(March - September 2006)**

Class	Total Dollar Value	% of Total Meds
Arthritis	3,250	1.2
Asthma/Allergy/Lung	20,957	7.5
Diabetes/Endocrine	20,645	7.4
Gastro-intestinal	18,573	6.7
Heart/Cholesterol/Stroke	34,857	12.5
Mental Health	82,712	29.7
Migraine/Other Pain	13,421	4.8
Other	62,734	22.5
Other Seizure	21,190	7.6
Total	278,342	99.9

**Insurance Status of Clients Served
(March - September 2006)**

Type of Coverage	Total # Served	% of Clients Served
None	436	80.1
County Social Services	44	8.1
Medicare	32	5.9
Private Insurance	12	2.2
Medicaid	6	1.1
Not Reported	14	2.6

**Demographic Composition of Clients Served
(March- September 2006)**

	Total # Served	% of Clients Served
Race/Ethnicity		
White (non Hispanic)	338	62.1
Black (non Hispanic)	137	25.2
Hispanic	50	9.2
Asian/Pacific Islander	1	0.2
Native American	7	1.3
Other	2	0.4
Not Reported	9	1.7
Gender		
Male	196	36.0
Female	344	63.2
Not Reported	4	0.7
Age		
Under 18	6	1.1
18-24 years	31	5.7
25-44 years	172	31.6
45-64 years	289	53.1
65 and over	36	6.6
Not Reported	10	1.8

III. Resource Analysis

A. Pinellas County

A resource analysis of Pinellas County community programs was conducted in August and September 2006. Twelve programs responded to a set of questions regarding the compassionate drug service they provide to area residents. The purpose of the analysis was to determine the extent of the need for services and the resources available to meet that need based on input from "community experts". The following programs completed the survey:

- American Lung Association
- Clearwater Free Clinic
- Daystar Life Center - Basic Needs Assistance
- Department of Vocational Rehabilitation
- Family Emergency Treatment Center
- Pinellas County Human Services Pharmacy Program
- Pinellas Village
- Religious Community Services - Food Bank
- St. Petersburg Free Clinic - We Help
- St. Petersburg Free Clinic Health Center
- St. Vincent de Paul - Free Meds
- Salvation Army - Clearwater

Caution must be exercised in drawing conclusions from the data due to inconsistencies in what data is collected and available from the programs.

Eligibility criteria varied from one agency to the next and included:

- Anyone with need for lung medication
- Adults and children who are patients of the clinic; no homeless people; must be uninsured and under 65; need proof of residency and citizenship
- Anyone in Pinellas with need; ineligible for other programs or would take too long and need is critical
- Adult Pinellas resident
- Anyone with need; must be documented citizen
- Age 18-65; not eligible for Medicare, Medicaid, county health insurance; low income
- Age 18-65; not eligible for Medicare, Medicaid, county health insurance; low income and working
- Serve children and adults; does not require Pinellas residency
- Physical, emotional, mental disability that interferes with employment; willingness to work; prefer persons who are currently employed
- Clients must live north of Ulmerton Road to the County line
- County resident, 100% FPL, \$2,000 in medical assets
- Residents who have no other avenue to pay for the medications

Programs imposed limitations on medications provided, such as:

- Pay for all lung medications and nebulizers
- No psychiatric, immunizations, narcotics, sedatives or tranquilizers
- Generally no controlled medications

- Provides psychiatric medications only; no controlled meds or ADD/ADHD medications
- No controlled substances
- Fills only antibiotic scripts written at a Pinellas emergency room
- All medications available through a pharmaceutical assistance program
- Only pays for antibiotics
- No restrictions (2 programs)
- Generics only formulary, limited coverage for over the counter medications with physician script, non-formulary medications and narcotics over the control limit must be preauthorized

The amount of assistance available per person varied:

- One time assistance for lifetime
- As needed
- Generally one time; some exceptions
- Temporary only; referred to another agency for long term
- Case by case
- Generally once per year, but not turned away if medical need
- One script up to \$100
- 10 per month unless override authorized
- Try to keep limit to \$100 per client

The total amount of assistance provided by the program in a one year period ranged from \$400 to \$4,480,168. One program reported no limit and several agencies chose not to disclose that information.

Programs were unable to provide consistent data on the number of clients served. Some did not collect the data or chose not to disclose it. Reported clients served varied greatly from 30 to 26,375.

Funding sources included Allegany Franciscan Ministries, Department of Education, Pinellas County Government, United Way of Tampa Bay, general fund, and donations. Some programs chose not to provide information about their funding source or indicated they had no funding and used volunteers.

Programs indicated the medications needed by their clients including:

- Albuterol and prednisone (asthma medications)
- Diabetic, hypertension, cholesterol, antibiotics
- Antibiotics, life sustaining medications for asthma, anxiety/depression, cholesterol, diabetes, hypertension, acid reflux, thyroid disease
- Non-controlled psych medications
- All types
- Antibiotics, medication for depression and ADD

Each program operated differently including:

- Prescriptions were filled at CVS and Florida Medical Supply which bill the program; clients were also referred to national prescription assistance website for long term needs.
- Some meds were given for donation from clinic's pharmacy; volunteer assisted clients obtain patient assistance program medications by filling out application

- Two volunteers assisted client with patient assistance program applications; center paid for medications when no other resource exists by sending a check for pharmacy with client
- Clients were given samples until patient assistance program medications were obtained
- Corporate office cut check to pharmacy filling prescription
- Check was written to pharmacy
- Clients were given a voucher to take to Neighborly Pharmacy
- Free medications obtained through patient assistance program using volunteers to assist client with application; paid for prescriptions on emergency basis until patient assistance program medications secured
- Payments made to program's vendors
- Scripts were filled at Publix by giving the client a voucher
- Prescriptions filled at contracted pharmacies in the county

B. Hillsborough County

A resource analysis of Hillsborough County community programs was conducted in October 2006. Two programs responded to a set of questions regarding the compassionate drug service they provide to area residents. The purpose of the analysis was to determine the extent of the need for services and the resources available to meet that need based on input from "community experts".

The following programs completed the survey:

- Brandon Outreach Clinic
- Hillsborough County Health Care Plan

Caution must be exercised in drawing conclusions from the data due to inconsistencies in what data is collected and available from the programs.

Eligibility criteria varied from one agency to the next and included:

- No insurance, no government assisted medical program and income below 200% FPL
- County resident whose income is up to 100% of FPL, does not have health insurance and whose assets meet asset criteria

Hillsborough Health Care Plan imposes restrictions on medications by dispensing pursuant to formulary, with case-by-case exceptions, and by requiring a co-pay based on income.

The amount of assistance available per person varied:

- Averages \$85 per client per month or \$1,020 per year
- Averages 4.68 prescriptions per client per month

The total amount of assistance provided by the Hillsborough County Health Care Plan in a one year period was \$14.5 million. Data was not available from the other agency that responded to our survey.

Hillsborough Health Care Plan reported 7,200 users (12,900 members) of the Pharmacy Program. The other responding agency did not provide client data.

The funding source for the Hillsborough Health Care Plan was sales tax. Data was not available from the other agency that responded to our survey.

Programs indicated the medications needed by their clients including: Advair, Avandia, Lexapro, Prilosec OTC, Glucose Test Strips, Singulair, Plavix, Zolof, Crestor, Depakote, Novolin Insulin, Seroquel, Lotrel, Geodon, Ambien, Combivent Inhaler, Risperdal, Effexor, and Diovan HCT

The Hillsborough Health Care Plan dispenses medications using Kash N Karry, Health Department and Medical Networks when approved by Pharmacy Benefits. Manager based on formulary. It also has Patient Assistance Program to secure free drugs from manufacturers. Data was not available from the other agency that responded to our survey.

IV. Allegany Franciscan Ministries Roundtable

On September 29, 2006 Allegany Franciscan Ministries (AFM) convened a Roundtable on the subject of prescription drug assistance. The overall purpose was to facilitate the exchange of information and ideas about the issue. Agencies represented at the Roundtable included:

Hillsborough County

- Judeo-Christian Health Clinic
- Hispanic Services Council
- St. Joseph's Hospital

Pinellas County

- Daystar Life Center
- Neighborly Care Network
- Pinellas County Human Services
- Pinellas Village
- Suncoast Health Council
- University of South Florida

Those present explained the role their respective agency played in meeting the need for prescription assistance in the local community. They also highlighted limitations in their program and identified issues/trends.

The discussion clearly recognized that need exists at several levels, i.e. emergency need for short term prescriptions to treat an acute illness (e.g. ear infection) as well long term chronic medications for treatment of conditions involving diabetes, high blood pressure, psychiatric illness, etc. For the long term chronic needs, clients also had a need for immediate assistance (average 30 days) until applications could be filed to secure compassionate drugs from a pharmaceutical assistance program on a long term basis. All present recognized the need to have a voucher system to meet the immediate needs while securing the long term assistance.

Participants also discussed the difficulty in knowing what resources exist at the local level and how to access those resources in a timely fashion. There were also

comments made regarding the difficulty in securing multiple drugs from multiple manufacturers which each have differing sets of requirements and forms. This complex situation is more difficult for persons who are ill and/or have issues such as low literacy, language barriers, cultural issues, visual impairments, or psychiatric conditions. The availability of trained staff/volunteers to guide the client throughout the process was critical to the success of receiving the needed drugs. It was also noted that this person could follow-up with the client to insure there are using the medications properly and not experiencing side effects, which could hinder their treatment compliance.

Coordination with hospital discharge planners, private and public health clinic staff was noted as being essential. Also the need to interface with providers of mental health services was noted since the need for psychiatric drugs is critical.

The group also explored the impact of other issues on the demand for medication assistance including: the Medicare Part D "doughnut hole", the increasing number of uninsured, the rising cost of co-payments, the needs of the undocumented, and the potential impact of Wal-Mart's \$4 generic pilot.

V. Issues Related to Service Delivery

Based on the community resource analysis and the AFM Roundtable several issues were identified

- A. **Undocumented Immigrants:** Programs serving undocumented immigrants are limited. For example, one program stated it would only provide life sustaining medications and another program would only assist if it was allowable under the patient assistance program requirements.
- B. **Drugs not Available under Patient Assistance Programs:** Not all drugs are covered by a patient assistance program and some are too expensive to purchase (e.g. Norvasq).
- C. **Fewer Free Samples:** Programs report that pharmaceutical representatives are providing fewer free samples of medications (e.g. Paxil, Zoloft).
- D. **Patient Assistance Program Access Limited under Medicare Part D:** Programs report that the number of patient assistance programs which serve the elderly who have Part D coverage has declined. Assistance is needed for Part D clients when they reach the coverage gap.
- E. **Demand for Assistance Increasing:** For example, one program reported that they averaged ten scripts in Quarter I but 19 in Quarter IV. This may lead to limitations on the amount of service provided.

One program reported that the elderly were requesting food and utility assistance because of property insurance and medical expenses.

A third program indicated an increase in the number of clients who have lost their insurance or cannot afford insurance. Additionally they are impacted by clients who can not pay their share of cost for the medically needy program or do to the Medicare Part D donut hole.

- F. **Standardized Patient Assistance Program Requirements/Forms:** Each manufacturer has a different set of guidelines and forms to use further complicating the process. In addition some agencies noted that they often have to resubmit application material multiple times.
- G. **Short Term versus Long Term Assistance:** Any program needs to provide a mechanism for both short term and long term assistance both to meet acute needs and the needs of clients waiting for approval from the manufacturer's programs.
- H. **Prescription Renewals:** A critical element in any program is a system to insure clients receive needed prescription renewals in a timely fashion.
- I. **Awareness on Part of ERs:** Emergency rooms need increased awareness of the difficulty in securing medications for indigent patients so they use care in prescribing several expensive brand name drugs rather than generic medications.
- J. **Formularies for Assistance Programs:** Each existing community based assistance program has a different formulary of which medications it will supply. This complicates referring clients to the right source.
- K. **Flexibility:** A client may have unsuccessfully tried less expensive medication. Flexibility is needed to meet clients' documented medical need.
- L. **Drug Inflation:** The rising cost of drugs impacts the ability of both individuals and programs to purchase medications.
- M. **Generic Programs by Stores:** The potential impact of discounted generic programs offered by Wal-Mart and Target are unknown at this time; however, access to low cost drugs can provide short-term relief as a long-term source of free medications is pursued.

VI. Community Partner Technical Advisory Team

On October 4, 2006, Suncoast Health Council, Inc. convened a Technical Advisory Team meeting with community-based agencies that have entered contractual agreements to expand access to health care and prescription drug services through a Health Access Network Demonstration (HAND) Project. Currently, the Health Access Network is limited three (3) sites in Pinellas County but the intent is to expand the network to include additional community-based agencies and safety net providers. Members of the Health Access Network include Community Health Centers of Pinellas, St. Petersburg Free Clinic, and Suncoast Health Council, Inc. The Health Council provides MedNet services to HAND partner sites; coordinates project activities across

partner sites; convenes and facilitates a Technical Advisory Team consisting of representatives from HAND partner sites, Bayfront Health Systems, Neighborly Pharmacy, and Pinellas County Government; and promulgates eligibility criteria and operating policies based on recommendations made by the Technical Advisory Team. Policies developed by the Advisory Team will serve as the foundation for a comprehensive community platform with which to address access to prescription drug services for low-income, uninsured residents in Pinellas County.

Initial discussions by the Technical Advisory Team focused on four (4) critical components of prescription drug access:

- Access to prescription drugs for chronic conditions (e.g., diabetes, hypertension, Lupus, etc.);
- Access to prescription drugs for acute, episodic conditions including infections (e.g., strep, ear infections, etc.);
- Access to prescription drug co-payments for Medicare Part D enrollees (i.e., seniors who are 'at the doughnut hole'); and
- Access to prescription drug education to assure patient safety.

VII. Recommendations

Based on input from the prescription drug roundtable and consensus reached at the Technical Advisory Team meeting, a comprehensive approach to prescription drug access must include the following policy considerations:

A. Short-Term Acute Conditions

Grant funds should be secured and set-aside to issue prescription vouchers to treat short-term acute conditions, including: bacterial and viral infection such as influenza; sexually transmitted diseases; gastrointestinal flare-ups; parasitic infection; dermatology conditions; dental abscesses arising from pending extractions; and allergic reactions. Vouchers to treat other acute conditions should be issued on a case-by-case basis as deemed appropriate by clinical staff and members of the community-based Technical Advisory Committee convened in conjunction with the Health Access Network Demonstration Project.

Eligibility for acute medication voucher access should be based on established eligibility requirements; specifically, acute medication voucher clients must:

- Be uninsured;
- Have a household income at or below 250% Federal Poverty Level (FPL); and
- Demonstrate strong intent to correct the acute condition (e.g., by taking the medication as prescribed; by returning for follow-up care; etc.).

B. Short-Term Vouchers for Chronic Conditions

Grant funds should be secured and set-aside to issue prescription vouchers for the short-term purchase (14-30 days) of medications to treat cardiovascular disease, pulmonary disease, and diabetes. Vouchers for medications to treat other diseases should be approved on a case-by-case basis as deemed appropriate by clinical staff and members of the community-based Technical Advisory Committee convened in conjunction with the Health Access Network Demonstration Project.

Eligibility for chronic medication voucher access should be based on established eligibility requirements; specifically, chronic medication voucher clients must:

- Be uninsured;
- Have a household income at or below 250% Federal Poverty Level (FPL);
- Demonstrate strong intent to manage their chronic disease (e.g., by starting a weight reduction/health education program, attending smoking cessation classes, etc.); and
- Begin working immediately with the MedNet Navigator to pursue long-term use of free pharmaceuticals through the MedNet Program.

C. Dispensing Safety

Medications secured for use by clients accessing primary care in a clinic-based setting should be shipped to the clinic and dispensed by the in-house pharmacy and/or appropriate clinical staff. Similarly, medications secured for use by clients accessing primary care at community-based physician offices (i.e., private health care providers) should be shipped to the prescribing physician unless the pharmaceutical manufacturer allows for home delivery or utilizes a coupon system, in which case the dispensing pharmacy can assure the appropriate dosage/quality of medications.

In situations where medications are dispensed in a clinic-based partner site setting, every effort should be made to assure access to compassionate use medications without cost to program clients.

D. Set Aside Fund for Serving Undocumented Immigrants

Grant funds should be secured and set-aside to issue prescription vouchers to treat short-term acute or chronic conditions of undocumented immigrants who do not qualify for prescription drug access through the pharmaceutical manufacturing industry. Similarly, grant funds should be secured and set-aside to purchase prescription drugs for undocumented immigrants through low-cost mail-order pharmacies (e.g., RX Outreach, etc.), if such pharmacies provide access to undocumented immigrants.

Eligibility for acute and chronic medication voucher and/or mail-order access for undocumented immigrants should be based on established eligibility requirements; specifically, undocumented immigrants must:

- Be uninsured;
- Have a household income at or below 250% Federal Poverty Level (FPL); and

- Demonstrate strong intent to correct the acute condition and/or manage their chronic disease (e.g., by starting a weight reduction/health education program, attending smoking cessation classes, etc.); and

E. Set Aside Fund for Clients Affected by Medicare Part D Donut Hole

Grant funds should be secured and set-aside to issue prescription vouchers to treat short-term acute or chronic conditions of 'doughnut hole' Medicare Part D recipients who do not qualify for prescription assistance through the pharmaceutical manufacturing industry.

Eligibility for short-term acute and chronic medication voucher access by Medicare Part D recipients should be based on established eligibility requirements; specifically, Medicare Part D clients must:

- Have a household income at or below 250% Federal Poverty Level (FPL);
- Be 'at the doughnut hole'; and
- Demonstrate a pattern of consistent prescription drug use for the management/treatment of chronic disease.

F. Marketing of Program

Grant funds should be secured and set-aside to assure the effective marketing of prescription drug access programs to potential clients, caregivers, community agencies and medical professionals. A detailed marketing plan including outreach mechanisms for each referral source should be in place. Outreach and training of emergency room staff should be a key component of the plan. Adequate resources should be allocated to keep all referral sources aware of the program, eligibility criteria, application process, formulary, etc.

G. Data Collection and Program Evaluation

Grant funds should be secured and set-aside to assure the effective collection and management of prescription program utilization data; specifically, data must include the use of a centralized data base to evaluate the effectiveness of program services on a quarterly basis. Adjustments to program design and operations should be based on findings from utilization reviews conducted by a community-based Technical Advisory Committee.

H. Ongoing Community Dialogue

Establishing a successful compassionate drug mechanism for each county requires ongoing community dialogue on the needs of the clients, the role of agencies and healthcare providers, and resources to carryout the program. While a Technical Advisory Committee can serve many of these functions, establishing a formal system to report to and from that Committee is critical.

Grant funds should be secured and set-aside to develop a detailed plan outlining the methods to be used (i.e. surveys, focus groups, town hall meetings) to gain community

input and insure that the input flows effectively between the community (i.e. clients, agencies, healthcare providers) and the Technical Advisory Committee.

VIII. Conclusion

While significant efforts have been made to increase the availability of primary care for low income, uninsured or medically under-served residents, there continues to be a lack of adequate resources dedicated to providing prescription drug access to this vulnerable population. Safety net providers continue to rely on acquiring free medications from pharmaceutical companies, but most providers lack the technical expertise required to manage the complicated and time-consuming application process.

Both Hillsborough and Pinellas Counties have several agencies which are attempting to meet the demand for prescription drug assistance; however, these agencies report that the demand for services is outpacing available resources. They also have identified issues which affect their ability to work effectively at the community level.

Research has demonstrated that a client's adherence to medication therapy promote effective management of chronic illnesses including heart disease, mental health disorders, diabetes, and asthma. Treatment adherence can reduce the demand on emergency rooms and primary care services.

An opportunity exists to alleviate this critical community need by establishing a unified approach to identifying/coordinating existing community resources and expanding program options to meet the unique prescription drug needs of vulnerable populations, including uninsured adults, undocumented immigrants, and under-served Medicare Part D recipients. A centralized system, which partners with existing safety net providers, would best serve the local community and its residents.

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