Introduction to Long Term Care: Meet the Stakeholders - A Panel Discussion

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Introduction to Long Term Care: Meet the Stakeholders - A Panel Discussion

Learning Objectives:

1. Discuss the practical challenges from a practitioner perspective of entering the Long Term Care market.

2. Review current legal issues for the LTC provider.

3. Discuss how to meet facility needs with the proper service package.

NATIONAL COMMUNITY PHARMACISTS ASSOCIATION
CONVENTION AND TRADE EXPOSITION

OCTOBER 15 - 19, 2005
FT. LAUDERDALE/BROWARD COUNTY
CONVENTION CENTER

INTRODUCTION TO LONG TERM CARE

Panel Discussion

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BIO - JEFFREY S. BAIRD, ESQ.

Jeffrey S. Baird, Esq., is the Chairman of the Health Care Group of the Amarillo, Texas based law firm of Brown & Fortunato, P.C. The firm's Health Care Group has a large national health care practice with clients throughout the United States. The Health Care Group represents durable medical equipment companies, pharmacies, drug wholesalers and repackagers, long term care facilities, home health agencies, hospitals, physicians and other health care providers. The Health Care Group represents clients in the areas of advising on fraud and abuse issues; defense of criminal and civil fraud investigations; defense of qui tam actions; corporate compliance; HIPAA compliance; mergers and acquisitions; joint equity arrangements, affiliations and alliances; reimbursement issues, including audits and requests for overpayments; provider and provider number issues; requirements pertaining to licenses, permits and certifications; survey certification and licensing issues; peer review and credentialing; pharmacy compounding; Food and Drug Administration regulatory issues; hospital operational issues; hospital medical staff relationships; and hospitals/health care organizations in transitional environments. The Health Care Group works closely with the Department of Justice, Office of Inspector General, Centers for Medicare and Medicaid Services, National Supplier Clearinghouse, Durable Medical Equipment Regional Carriers, Food and Drug Administration, and other federal and state regulatory agencies. Mr. Baird has authored numerous articles and is a frequent lecturer throughout the country. He earned a B.B.A. from the University of Iowa and received his law degree from the University of Tulsa College of Law. Mr. Baird is Board Certified in Health Law by the Texas Board of Legal Specialization.

BIO - DENISE M. FLETCHER, ESQ.

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BIO – CHARLES BELL

Charles Bell has been in Long Term Care for 12 years. During that time he has served as an Administrator in both Skilled Nursing and Assisted Living settings. He also served 3 years as a Vice President of Operations for a Management Company where he had direct responsibility for 9 Skilled Nursing Facilities. Mr. Bell currently serves as Senior Executive Director for Tandem Health Care Of Kissimmee, a 120 bed Skilled Nursing and Rehabilitation facility located in Kissimmee, FL. He has served with Tandem Health Care for 3 years. Mr. Bell has vast experience in managing successful Long term care operations at all levels of Skill and size. Mr. Bell was born in Pasadena, Ca and moved to Florida with his family in 1976. He grew up in Orlando, FL. Mr. Bell received an Undergraduate Degree in Business Administration from Stetson University, Deland, FL in 1992. Mr. Bell graduated from the Mercantile Corporation's Management Training program in 1993 where he received extensive training in both Customer Service / Employee relations. Mr. Bell lives in Gotha, FL. Has been married for 10 year to Amy Bell and has 2 girls, Sophie 6 and Chloe 4.

BIO – SCOTT G. HUGHES, R.PH.

Scott G. Hughes, R.Ph. is a Partner and Corporate Vice President of MemberHealth, Inc., a full service pharmacy benefit management company based in Cleveland, Ohio.

MemberHealth provides a broad range of PBM services nationwide with key focus on the senior marketplace through initiatives in the Medicare Discount Drug Card and various State Pharmacy Assistance Programs.

MemberHealth has received CMS approval as a Medicare Part D PDP (Prescription Drug Program) in all 34 Regions nationwide plus Puerto Rico and the Virgin Islands.

MemberHealth is one of 2 companies which received a special endorsement to service the long term care population under the Medicare Discount Drug Program and has thus developed unique expertise in working with the LTC provider community.

Mr. Hughes' professional background includes more than 25 years of corporate experience in sales, marketing, and operations management roles in the drug wholesaler, chain drug and pharmacy benefit management segments of the pharmacy industry.

Mr. Hughes is a graduate of Rutgers University College of Pharmacy with Bachelor of Science and Pharmacy Degrees.

His professional and organizational experience includes extensive participation in national and state pharmacy associations: NACDS, NCPDP, NCPA and the Ohio Pharmacy Association.

INTRODUCTION TO LONG TERM CARE

I. Overview of the Long Term Care ("LTC") Pharmacy

A. The uniqueness of LTC pharmacists' work

among health professionals in institutional settings foster a team approach to drug therapy management in the nursing home in which each health professional's distinctive expertise works to serve residents. As several studies in nursing homes have shown, in a large majority of cases, physicians heed the counsel of pharmacists on drug therapy recommendations.

LTC pharmacists' involvement in formal quality assurance and quality improvement activities in nursing homes is also unique. Because drug therapy is the primary mode of treatment in LTC settings, the expertise of the pharmacist is used to set nursing-homewide policies and protocols. Moreover, LTC pharmacists also perform a continuous quality improvement function by identifying problems in, for example, medication administration and designing programs to teach nurses how to rectify these problems.

Progressive nursing homes find formal interdisciplinary care planning essential to guaranteeing optimal patient outcomes. In these settings, all the health professionals who care for patients review the care plans of individual patients. This forum allows for assessment of the interdependence of treatments, medications, diet, exercise, and any other factors that affect the patient's quality of life. In this manner, care plans can be modified to address changes in residents' conditions.

3. LTC pharmacists' close and regular contact with physicians enhances prescribing.

Through a number of approaches, pharmacists work with physicians to enhance prescribing in ways that improve quality and control costs. The formalized chart review that is part of drug regimen review offers an opportunity for pharmacists and physicians to discuss changes to drug therapy (specific drugs, dosages, dosage intervals) that optimize patient care. Drug use evaluation/drug utilization review, in which the pharmacist systematically analyzes aggregate patterns of drug usage in a facility and recommends modifications using predetermined criteria, also helps physicians enhance prescribing. Generic substitution or therapeutic interchange, which includes situations when a more costly drug is substituted with a less costly drug that achieves the same therapeutic result, is more easily accomplished in a setting where pharmacists and physicians can confer regularly. Formulary development and management also enhances prescribing because physicians and pharmacists can formulate and control jointly a list of drugs and the specific guidelines under which a drug should be prescribed. Such a formulary in a LTC setting must follow from an understanding of the special therapy needs of the institutionalized frail elderly.

4. LTC pharmacists educate health professionals formally and informally on drug therapy issues.

LTC pharmacists' unique expertise enables them to educate other health professionals on a range of drug-therapy issues in the LTC setting. They conduct regular in-service training to nurses, dietitians, and physicians. Topics might include training the nursing staff to monitor patients with certain maladies and certain drug therapies; educating staff on the most efficient procedures for handling and administering medications; and training staff to care for high-acuity patients who would otherwise have to be rehospitalized. In addition, LTC pharmacists make themselves available to answer questions and address issues that physicians, nurses, and others working in the nursing home might have.

5. LTC pharmacists provide continuous care to nursing home residents.

The LTC pharmacist conducts ongoing review of residents' drug regimens, as revisions to the therapy are often warranted when a resident's condition changes. This is possible in the nursing home because the unique exchange of information among physicians, pharmacists, and nurses is continuous, as opposed to being limited to an episode of dispensing. If a resident's condition does not improve, the pharmacist will discuss changes to treatment with nurses and physicians.

6. LTC pharmacists are committed to providing products and services 24 hours a day, 365 days a year.

LTC pharmacies are designed to address emergency as well as regular needs. They have developed special practices with protocols that give them the ability to provide medications to the nursing homes within two hours. This service is built on the knowledge that the frail residents of nursing homes may require care in acute settings if their drug therapy needs are not met immediately.

7. LTC pharmacists use unique controlled dispensing systems to ensure that nursing home residents receive the right drugs at the right time and in the proper dosage.

LTC pharmacies and their practitioners have developed and use specialized dispensing systems uniquely suited to the needs of nursing home residents. These systems allow the nursing staff to administer medications with ease and in proper premeasured doses, which enhances compliance, saves time, prevents medication errors, and permits easy tracking of medication use to maintain accountability. Mobile medication carts help ensure that residents receive the proper medications at the proper times.

8. LTC pharmacists allow unused, unopened products to be returned for credit.

With return of unused, unopened drugs, frequent medication changes do not result in unused products going to waste. It is particularly cost-effective in a setting that must respond quickly to changing patient needs. Note, however, that some states do not permit such crediting.

9. LTC pharmacists' services are comprehensive in scope and intensity.

The uniqueness of LTC pharmacists lies not only in the range of services they deliver but in the thoroughness with which they perform those services. This comprehensiveness is necessitated by the populations they serve. Frail, often elderly people with multiple chronic conditions need and deserve much more attention than healthy people with a single condition. The more medications a nursing home resident takes, the greater the chance for adverse consequences. As residents' conditions change often, constant scrutiny and frequent updating of drug regimens are warranted. Attention to individual residents' needs must also be supplemented with education on and oversight of the drug therapy needs and protocols of the entire institution.

D. Statistics

1. Today there are 38 million seniors in the United States; by 2030, that number will rise to 75 million.

2. Every day in the United States, another 6,000 people reach the age of 65.

3. There are 5.5 million seniors with long-term disabilities in the United States. This figure is expected to increase to 10 million by the year 2020, and to 20 million by 2040.

4. Life expectancy at age 85 has increased 24% since 1960; and is projected to increase another 44% by 2040, with an accompanying increase in the incidence of conditions such as hip fractures and Alzheimer’s disease.

II. Role of Consulting Pharmacist

A. For millions of senior citizens and individuals with chronic illnesses, consultant pharmacists play a vital role in ensuring optimal drug therapy. In their role as medication therapy experts, consultant pharmacists take responsibility for their patients’ medication-related needs; ensure that their patients’ medications are the most appropriate, the most effective, the safest possible, and are used correctly; and identify, the safest possible, and are used correctly; and identify, resolve, and prevent medication-related problems that may interfere with the goals of therapy.

B. Consultant pharmacists manage and improve drug therapy and improve the quality of life of the senior population and other individuals residing in a variety of environments, including hospitals, nursing facilities, subacute care and assisted living facilities, psychiatric hospitals, hospice, and home- and community-based care.

C. While medications are probably the single most important factor in improving the quality of life for older Americans, the nation's seniors are especially at risk for medication-related problems due to physiological changes of aging, higher incidence of multiple chronic diseases and conditions, and greater consumption of prescription and over-the-counter medications.

D. The economic impact of medication-related problems in persons over the age of 65 now rivals that of Alzheimer's disease, cancer, cardiovascular disease, and diabetes. Medication-related problems are estimated to be one of the top five causes of death in that age group, and a major cause of confusion, depression, falls, disability, and loss.

E. Estimated Annual Cost of Medication Related Problems

1. $76.6 billion among the ambulatory population

2. $20 billion in acute-care facilities

3. $7.6 billion in nursing facilities

F. Consultant pharmacists are committed to caring for the well-being of each individual, taking into account the complex interrelationships between disease states, nutrition, medications, and other variables.

G. Consultant pharmacists counsel patients, provide information and recommendations to prescribers and caregivers, review patients' drug regimens, present in-service educational programs, and oversee medication distribution services.

H. In addition to these basic responsibilities, consultant pharmacists provide a wide range of other primary care services to the nation's seniors, including pain management counseling, pharmacokinetic dosing services, intravenous therapy, nutrition assessment and support, and durable medical equipment.

I. The ASCP-sponsored Fleetwood Project study found that consultant pharmacists' drug regimen review services in the nation's nursing facilities improve therapeutic outcomes by 43% and save as much as $3.6 billion annually in costs associated with medication-related problems.

J. Statistics

1. Adverse drug reactions are among the top five greatest threats to the health of seniors.

2. 28% of hospitalizations among seniors are due to adverse drug reactions.

3. 32,000 seniors suffer hip fractures each year due to falls caused by medication-related problems.

4. The elderly account for 12.7% of the U.S. population, but consume approximately 34% of total prescriptions.

5. On average, individuals 65 to 69 years old take nearly 14 prescriptions per year; individuals aged 80 to 84 take an average of 18 prescriptions per year.

6. The number of seniors needing LTC is projected to rise to 13.8

7. There are more than 1.6 million nursing home beds in the United States; this represents an increase of over 25% since 1980.

K. "Consultant Pharmacist" is still commonly thought of as a "nursing home pharmacist." While that narrow definitions describes a field of practice that is among the most complex, challenging, and rewarding in the pharmacy profession, it no longer accurately defines what consultant pharmacy practice has evolved into over the past 30 years. What distinguishes consultant pharmacy practice today are not government regulations or institutional settings, but rather, the complexity of the health care needs of the patients they serve. They are all at high risk.

III. Collaborative Practice

A. Collaborative practice agreements are being used, or considered for use, in numerous states throughout the United States, as a way of optimizing patient care by expanding the involvement of the pharmacist.

B. A collaborative practice agreement is a voluntary, written agreement between a pharmacist and a prescriber that permits expanded authority for the pharmacist, such as the ability to initiate or modify drug therapy and order laboratory tests. Collaborative practice agreements are intended to optimize patient care outcomes, and may include protocols, practice guidelines, care plans and formulary systems.

IV. Counseling of Geriatric Patients

A. Counseling is one tool that pharmacists can use to reduce or prevent medication-related problems. Through counseling, pharmacists have the potential to improve patient compliance with medication regimens, decrease hospital admissions due to adverse

medication events, improve the cost-effectiveness of the medication therapy, and improve the quality of their patients' lives. In providing counseling, the LTC pharmacist should adhere to the following guidelines:

1. Pharmacists should counsel all geriatric patients to the extent possible, considering their special needs.

2. Pharmacists have a duty to assess indication, efficacy, safety and outcomes of medication therapy as part of the counseling process and ensure patients' understanding of medication regimens.

3. Pharmacists should collaborate with other appropriate interdisciplinary team members to determine what specific information and counseling are required in each patient care situation.

B. Studies indicate that the substantial economic and human costs associated with inappropriate medication use are likely to exceed the initial outlays for medication therapy. Consequences of medication-related problems include increased physician visits, additional visits to allied health care professionals, additional medication, additional laboratory tests, increased hospitalization, additional treatment of new medical problems, and increased morbidity and mortality.

C. Counseling the elderly poses a challenge to pharmacists. Geriatric patients are at greater risk of encountering medication-related problems because of their higher rate of medication use, more complex multidrug regimens, and changed pharmacodynamics. Other factors contributing to medication-related problems in the elderly include physical limitations, cognitive impairment, economic issues, and noncompliance.

D. Guidelines for Counseling

1. Knowledge and Skills

Pharmacists should possess the following knowledge and skills to effectively counsel the geriatric patient:

a. Current knowledge of geriatric pharmacotherapy and aging

b. Knowledge of the geriatric patient's culture and attitude toward health and illness

c. Awareness of patient's sensory or cognitive impairments

2. Pharmacist and patient roles

Clarify for the patient that pharmacists have an appropriate and important

role in providing education and counseling. The patient should be encouraged to be an active participant.

a. Pharmacist's role

(1) Verify that the patient has sufficient understanding, knowledge, and skill to follow the pharmacotherapeutic regimen and monitoring plan. This may include disease information.

(2) Seek ways to motivate the patient to learn about the treatment and to be an active partner in care.

(3) Collaborate with other appropriate interdisciplinary team members to determine what specific information and counseling are required in each patient care situation.

b. Patient's/Caregiver's role

(1) Adhere to the pharmacotherapeutic regimen.

(2) Monitor for medication effects.

(3) Report experiences to pharmacists or other members of the interdisciplinary team.

(4) Seek information and present concerns that may make compliance difficult.

3. Process steps for counseling

a. Steps in the patient education and counseling process may vary according to needs of the individual, environment, and practice setting.

b. Establish a relationship that will maximize effective communication by demonstrating genuine interest in the person, acceptance, and establishing rapport.

c. Address people using their preferred name.

d. Introduce yourself as a pharmacist, explain the purpose and expected length of the session, and obtain the patient's agreement to participate.

e. Determine patient-specific barriers to communication and implement a strategy to overcome barriers.

f. Assess the patient's knowledge about health problems and medications, physical and mental capability to use the medications appropriately, and attitude toward the health problems and medication.

(1) Ask open-ended questions about each medication's purpose and what the patient expects.

(2) The patient should be asked to describe or show how he has been using his medications. The patient should also be asked to describe any problems, concerns, or uncertainties he is experiencing with his medications. Routinely reevaluate.

(3) If a patient is experiencing problems with the medication, gather appropriate data and assess the problems. Then adjust the pharmacotherapeutic regimens according to protocols or notify the prescribers.

g. Provide information orally and use visual aids or demonstrations to fill the patient's gap in knowledge and understanding. Show the patient the colors, sizes, shapes, and markings on oral solids. For oral liquids and injectables, show patients the dosage marks on measuring devices. Demonstrate the assembly and use of administration devices such as nasal and oral inhalers. As a supplement to face-to-face oral communication, provide written handouts to help the patient recall the information.

h. Use active listening skills, good eye contact, and gestures where appropriate.

i. Observe nonverbal cues such as body language, behavior or facial expression, for reactions.

j. Give support, encouragement and feedback.

4. Special considerations in communicating with the elderly

a. Focus on abilities, rather than disabilities.

b. Assess individually and reassess often.

c. Use family or caregiver as a resource when the person is unable to give information.

d. Consider environment.

Education and counseling are most effective when conducted in a room or space that ensures privacy and opportunity to engage in

confidential communication. Patients, including those who are disabled, should have easy access and seating. Space and seating should be adequate for family members or caregivers. The design and placement of desks and counters or beds and wheelchairs should minimize barriers to communication. Distractions and interruptions should be few, so that patients and pharmacists can have each other's undivided attention. For example, in the home or institutional setting a loud radio or television may interfere with the counseling process. The environment should be equipped with appropriate learning aids, e.g., graphics, anatomical models, medication administration devices, memory aids, written material, and audiovisual resources.

e. Be aware of the potential for interference in communication abilities due to emotion, anxiety, anticipation, fatigue or pain.

f. Adjust the pace, and allow adequate time for response.

g. Employ a variety of communication media, as appropriate (e.g., signs, pictures or other aids).

h. Assess comprehension. Restate the patient's statements to ensure comprehension.

i. Adapt goals to what the patient can comprehend.

j. Be simple, but respectful, and reinforce with non-verbal cues.

k. Return when the patient is more receptive if there is a lack of response or cooperation.

l. Give simple, relevant information.

5. Consider "alternative" approaches based on special needs.

a. Aphasic

Facilitate communication with the aphasic patient by using writing pads, signs, signals, pictures, and gestures.

b. Hearing Impaired

(1) Eliminate as much background noise as possible.

(2) Determine if the patient wears a hearing aid and that it is present and functioning.

(3) Augment oral communication with other methods, e.g., writing, pictures, signs, and gestures.

(4) Face the person directly to achieve eye contact and enable lip reading.

(5) Do not cover your mouth or turn away when speaking.

(6) Speak slowly and clearly without exaggeration or shouting.

(7) Evaluate understanding frequently and rephrase if necessary.

(8) Focus on the main subject without unnecessary detail.

c. Visually Impaired

(1) Determine if patient wears glasses, contacts or other visual correction device.

(2) Position what needs attention so that it is in the center of the visual field.

(3) For printed communication, use black printing on white or off-white paper and larger font sizes.

(4) Be creative about methods of communicating, including talking books, radio and tapes.

(5) Speak as you approach the person so that he/she knows you are there. Introduce yourself and use touch, if the person does not object.

(6) Sit at the same level, and face them during the conversation. Give clues to relevant aspects that they may not be able to see.

d. Cognitive impairment

(1) Gain the patient's attention.

(2) Address one topic at a time.

(3) Give simple, relevant information.

(4) Allow the patient to feel in control. Manner, tone of voice, and body language can convey power and authority.

(5) Use a calm matter of fact approach, with clear and distinct verbal communication.

(6) Adapt to disease related language and memory deficits.

6. Content

The content of an education and counseling session may include the information listed below, as appropriate for each patient's pharmacotherapeutic regimen, monitoring plan, and patient's special needs. The decision to discuss specific pharmacotherapeutic information with an individual patient must be based on the pharmacist's professional judgment. The pharmacist's responsibility is to ensure that the patient understands the intended use of their medications, the goals of therapy, and safety concerns and convenience of use. The following points are applicable to both prescription and nonprescription medications. Pharmacists should counsel patients in the proper selection of nonprescription medications.

a. The medication’s trade name, generic name, common synonym, or other descriptive name(s) and, when appropriate, its therapeutic class and efficacy.

b. The medication’s use and expected benefits and action. This may include whether the medication is intended to cure a disease, eliminate or reduce symptoms, arrest or slow the disease process, or prevent the disease or a symptom.

c. The medication's expected onset of action and what to do if the action does not occur.

d. The medication's route, dosage form, dosage, and administration schedule (including duration of therapy).

e. Directions for preparing and using or administering the medication. This may include adaptations to fit patients' lifestyles or work environments.

f. Action to be taken in case of a missed dose.

g. Precautions to be observed during the medication's use or administration and the medication's potential risks in relation to benefits. For injectable medications and administration devices, concerns about latex allergy may be discussed.

h. Potential common and severe adverse effects that may occur, actions to prevent or minimize their occurrence, and actions to take if they occur, including notifying the prescriber, pharmacist, or other health care provider.

i. Techniques for self-monitoring of pharmacotherapy.

j. Potential medication-medication (including nonprescription), medication-food, and medication-disease interactions or contraindications.

k. The medication's relationships to radiologic and laboratory procedures (e.g., timing of doses and potential interferences with interpretation of results).

l. Prescription refill authorizations and the process for obtaining refills.

m. Instructions for 24-hour access to a pharmacist.

n. Proper storage of the medication.

o. Proper disposal of contaminated or discontinued medications and used administration devices.

p. Any other information unique to an individual patient or medication.

Additional content may be appropriate when pharmacists have authorized responsibilities in collaborative disease management for specified categories of patients. Depending on the patient's disease management or clinical care plan, the following may be covered:

a. The disease: whether it is acute or chronic and its prevention, transmission, progression, and recurrence.

b. Expected effects of the disease on the patient's normal daily living.

c. Recognition and monitoring of disease complications.

7. Documentation

Pharmacists should document education and counseling in patients' permanent medical records as consistent with the patients' care plans and applicable policies and procedures, and state and federal laws. When pharmacists do not have access to patients' medical records, education and counseling may be

documented in the pharmacy's patient profiles or on a specially designed counseling record.

The pharmacist should record that counseling was offered and was accepted and provided or refused and the pharmacist's perceived level of the patient's understanding. As appropriate, the content should be documented (for example, counseling about food-medication interactions). All documentation should be safeguarded to respect patient confidentiality and privacy and to comply with applicable state and federal laws.

V. Pharmaceutical Care

A. Pharmaceutical care is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. These outcomes are: cure of a disease, elimination or reduction of a patient's symptomatology, arresting or slowing of a disease process, or preventing a disease or symptomatology.

B. Pharmaceutical care involves the process through which a pharmacist, in cooperation with a patient and other health professionals, designs, implements, and monitors a pharmaceutical care plan that will produce specific therapeutic outcomes for the patient. This in turn involves three major functions performed by the pharmacist: identifying potential and actual drug-related problems, resolving actual drug-related problems, and preventing potential drug-related problems.

C. Pharmaceutical care is a necessary element of health care that should be integrated with other elements. Pharmaceutical care is, however, provided for the direct benefit of the patient, and the pharmacist is responsible directly to the patient for the quality of that care. The fundamental relationship in pharmaceutical care is a mutually beneficial exchange in which the patient grants authority to the provider and the provider gives competence and commitment (accepts responsibility) to the patient.

D. The fundamental goals, processes, and relationships of pharmaceutical care exist regardless of practice settings.

1. The basis of pharmaceutical care is responsibility and accountability to patients for the outcome of their drug therapy.

2. The overall goal of pharmaceutical care is to maintain patients at the highest possible level of functional and psychosocial well-being through optimal management of drug therapy.

3. Pharmaceutical care requires continuity of care between different practice settings.

E. Pharmaceutical care involves the pharmacist in three major functions on behalf of the patient: identifying potential and actual drug-related problems, resolving actual drug-

related problems, and preventing potential drug-related problems. A drug-related problem is an event or situation involving drug therapy that actually or potentially interferes with an optimum outcome for a specific patient. Drug-related problems include:

1. Untreated indications. The patient has a medical problem that requires drug therapy but is not receiving a drug for that indication.

2. Improper drug selection. The patient has a drug indication but is taking the wrong drug, or is taking a drug that is not the most appropriate for the special needs of the patient.

3. Subtherapeutic dosage. The patient has a medical problem that is being treated with too little of the correct medication.

4. Failure to receive medication. The patient has a medical problem that is the result of not receiving a medication due to economic, psychological, sociological, or pharmaceutical reasons.

5. Overdosage. The patient has a medical problem that is being treated with too much of the correct medication.

6. Adverse drug reactions. The patient has a medical problem that is the result of an adverse drug reaction or adverse effect.

7. Drug interactions. The patient has a medical problem that is the result of a drug-drug, drug-food, or drug-laboratory test interaction.

8. Drug use without indication. The patient is taking a medication for no medically valid indication.

9. Treatment failures. The patient has a medical problem that is being treated with a medication that is generally considered appropriate for the indication, but the desired therapeutic outcome is not achieved.

F. Pharmaceutical Care Plan

The pharmacist designs, implements, and monitors a pharmaceutical care plan for each patient who identifies desired therapeutic and/or functional outcomes for each medication prescribed and potential and/or actual drug-related problems. The patient is assessed by the pharmacist at appropriate intervals for progress toward the therapeutic and/or functional goals, and occurrence and resolution of drug-related problems. The pharmacist continuously updates the pharmaceutical care plan with patient-specific information and recommends modifications in therapy. The pharmaceutical care plan is separate from, but developed in conjunction with, the patient's overall plan of care, when one exists.

VI. Use of Psychotherapeutic Medications in Older Adults

A. Psychotherapeutic medications are among the most commonly prescribed medications in older adults. When used appropriately, these agents can play a key role in maintaining functional status and improving the quality of life of older adults. However, studies have demonstrated that these medications are often used inappropriately. For example, depression is often underdiagnosed and undertreated in older adults.

B. Some psychotherapeutic medications are overused or given in excessive dosages. In nursing facilities, regulations from CMS have increased attention and oversight regarding use of these agents.

C. Guidelines

1. Older adults should be screened for presence of affective, cognitive and other psychiatric disorders.

Older adults are at higher risk for affective and cognitive disorders. Health professionals, including physicians and pharmacists, who interact with older adults, should be alert for signs of common psychiatric disorders among older adults, including depression and dementia. When appropriate, the health professional should administer the screening tools or the patient should be referred to another health professional for screening. These screening tools are used to determine the need for further assessment. Commonly used screening instruments for this population include:

a. Folstein Mini-Mental Status Exam (MMSE)

b. Geriatric Depression Scale (GDS)

c. Cornell Scale for Depression in Dementia

Psychiatric disorders are especially common among the frail elderly who reside in nursing facilities and assisted living facilities. It has been estimated that 25-30% of nursing facility residents have depression. Some level of cognitive impairment is present in over half of nursing facility residents, with some studies showing that up to 80-90% of nursing facility residents exhibit at least one psychiatric disorder. Residents of assisted living facilities also have a high prevalence of depression and cognitive impairment. The average age of assisted living residents is similar to that of the nursing facility population.

Therefore, residents should be screened soon after admission for depression and cognitive impairment. Those who fail the screening should be referred for more thorough evaluation by a qualified health professional. In

addition, screening instruments should be administered when undiagnosed residents exhibit possible manifestations of dementia or depression.

2. Older adults who exhibit symptoms of psychiatric disorders should be thoroughly assessed by a qualified health care professional.

a. A qualified health professional should be consulted for assistance in evaluating older adults with behavioral symptoms or other psychiatric symptoms. Health professionals and caregivers of older adults should be trained to recognize common symptoms of underlying psychiatric disorders. In many cases, the initial symptom or problem may be an indication of an underlying psychiatric disorder. For example, insomnia can be an indicator of depression.

b. Behavioral manifestations should be recognized as symptoms, rather than as a distinct problem. All behavior is purposeful. Problem behaviors, such as hitting, require thorough evaluation to investigate an underlying cause. The explanation may be a physical problem, such as a toothache or fecal impaction in a demented person. In other cases, the problem may be a manifestation of an adverse reaction from a medication. For this reason, older adults who exhibit behavioral symptoms should always have an evaluation of their drug regimen to identify possible medication-related causes of these symptoms.

c. As part of the comprehensive assessment process, treatment goals should be established. These goals should be specific to the individual patient, and should be based upon the assessment and the patient's diagnosis.

d. In the institutional setting, an interdisciplinary approach is often best suited to evaluating and treating psychiatric and behavioral disorders. The attending physician, nurse, consultant pharmacist, social worker, medical director, and geriatric psychiatrist each have a contribution to make in evaluating and managing these symptoms. In addition, input from caregivers, facility staff, and relatives of the older adult can all be useful.

3. Behavioral symptoms in older adults should be objectively and quantitatively monitored by caregivers or facility staff and documented on an ongoing basis. When possible, psychiatric symptoms should also be monitored in this fashion.

a. When behavioral or psychiatric symptoms are observed, it is important to carefully define and document the behavior. All persons with behavioral symptoms should be monitored, even if not taking medications. Objective and quantitative monitoring of target behaviors will permit evaluation of whether the behaviors are improving or getting worse over a

specified time frame. Behavior monitoring also permits evaluation of the effectiveness of interventions, including medication.

b. Documenting the details surrounding each episode of the behavioral symptom provides information to assist in evaluation of underlying causes of the behavior. The behavior monitoring system should capture information about the location and time of behavior symptoms and allow for the determination of precursors to the behavior. For example, does the target behavior always occur in the same room? Does it always happen at the same time of day? Does the behavior always happen when the same person is present? What is the pattern to the behaviors?

c. When multiple persons are observing the resident, such as in a LTC facility, a specific definition or description of the target behavior will ensure that all observers are documenting the same behavior. The use of vague descriptors, such as the term "agitation", should be avoided. Whether a behavior monitoring form is used, or the information is documented in progress notes, the important factor is that adequate information be captured to allow analysis of the behaviors. Simply counting the number of episodes of target behaviors does not usually provide sufficient information to examine patterns and underlying causes of behaviors.

4. If the behaviors do not present an immediate serious threat to the patient or others, the initial approach to management of behavioral symptoms in older adults should focus on environmental modifications, behavioral interventions, psychotherapy or other nonpharmacologic interventions.

a. Once the older adult has been assessed and goals of therapy have been established, strategies for reducing behavioral symptoms should be planned and implemented. General nonpharmacologic interventions can often be successful in preventing or reducing behavioral symptoms.

b. A general principle of managing behavioral symptoms in older adults is to use the least intrusive strategies first. If these are ineffective, or only partially effective, then medications may be added to the other strategies that are in place. The adjunctive use of psychotherapeutic medications may improve the overall response to non-pharmacologic interventions or psychotherapy. Medications would only be used as first line therapy in acute situations where the resident is at immediate risk of harming himself or others.

5. When medications are indicated, select an appropriate psychotherapeutic agent, considering effectiveness of the medication and risk of side effects.

a. Older adults are especially vulnerable to adverse drug effects as a result of their multiple chronic diseases, use of multiple concomitant medications, and the pharmacokinetic and pharmacodynamic changes that accompany aging. For these reasons, prescribers need access to the full armamentarium of psychotherapeutic agents in order to customize drug therapy for each individual. For example, the atypical antipsychotics generally have fewer side effects than the typical antipsychotics. The atypical agents are often preferable in older adults, especially for long-term use.

b. Some of the older psychotherapeutic medications should be avoided for use in older adults. For example, amitriptyline and doxepin have been noted to be no more effective than other agents but have high anticholinergic side effects. The use of antihistamines (e.g. diphenhydramine) as hypnotic agents should be avoided in the elderly for the same reason.

c. Accurate diagnosis of the psychiatric disorder is a necessary first step in the selection of an appropriate psychotherapeutic agent. The agent selected should be indicated for the condition that has been diagnosed. In addition, each patient's drug regimen should be evaluated for potential contraindications and clinically significant drug interactions prior to initiating psychotherapeutic medication.

d. From among the effective agents available, the agent with the least potential for intrusive side effects should be selected. If two or more agents are considered equivalent on the basis of efficacy and side effects, cost may be considered in making the final selection.

e. An important factor in selection of an appropriate pharmacologic agent is consideration of the patient’s ability to adhere to the prescribed therapy. Factors that may affect patient adherence to therapy include the number of times per day the medicine must be administered; the patient’s ability to afford the cost of the therapy; and side effects of therapy.

f. Prior to initiation of therapy, the patient and/or caregiver should be informed of potential benefits and risks of medications, sufficient to participate in the decision making process.

6. Begin medication at the lowest appropriate dosage and increase the dose gradually.

a. A general principle of geriatric pharmacotherapy is to start low and go slow. This is especially applicable to psychotherapeutic agents. Except in urgent situations, these medications should be started at a low dose and gradually increased until the therapeutic effect is achieved.

b. It is also important to recognize that in some cases, the onset of full therapeutic effect may be delayed. Adequate time should be allowed before concluding that dosage increases are warranted or that the medication is ineffective.

c. Certain psychotherapeutic medications may be used on an “as needed” basis. These include short acting benzodiazepines (e.g. lorazepam, oxazepam) and hypnotics (e.g. temazepam). When psychotherapeutic medications are used PRN, the circumstances for use of the medication should be clearly delineated. Vague orders, such as "PRN agitation", should be avoided. In general, appropriate nonpharmacologic interventions should be attempted prior to use of PRN medications.

7. Monitor the patient for therapeutic response from the medication and for adverse drug reactions.

a. Individuals who take psychotherapeutic medications should be monitored to determine whether the medication is effective. Therapeutic goals should be established at the beginning of therapy. Symptoms and target behaviors should be identified and monitored on an ongoing basis.

b. Individuals taking psychotherapeutic medications should be continually monitored for adverse drug reactions. Monitoring tools, such as the Abnormal Involuntary Movement Scale (“AIMS”) in patients taking antipsychotic medications, can be useful for evaluating adverse drug reactions. The prescriber should be informed when significant adverse effects are noted.

c. In nursing facilities, the Minimum Data Set (”MDS”) can be an effective tool for monitoring effectiveness and adverse effects of psychotherapeutic medications. Consultant pharmacists should take advantage of available resources to learn to use the MDS as part of the drug regimen review process.

d. Patients, caregivers, and health professionals should be educated regarding the expected therapeutic goals, common side effects, and infrequent but serious adverse effects of psychotherapeutic medications, such as neuroleptic malignant syndrome. Input from all caregivers and health professionals is helpful for effective monitoring of the patient.

8. The psychotherapeutic medication regimen should be routinely re-evaluated for the need for continued use of medication, dosage adjustments or a change in medication.

a. Particularly in cognitively impaired individuals, psychiatric and behavioral symptoms tend to resolve over time. However, individuals diagnosed with psychiatric disorders such as bipolar disorder or major depressive disorder may require long term psychotherapeutic drug therapy to maintain their highest functional abilities.

b. Because of the variability of many psychiatric disorders and the potential for adverse drug reactions, it is important to re-evaluate the psychotherapeutic drug regimen at appropriate intervals. When a dosage reduction is indicated, medication doses should be reduced gradually to prevent acute exacerbations of the underlying condition. In many cases, the patient can be maintained on a lower dose of the medication, or it may be possible to discontinue the medication entirely.

VII. Federal Anti-Fraud Legal Guidelines

A. Statutes

1. Medicare/Medicaid Anti-Kickback Statute (42 U.S.C. § 1320a-7b) (“anti-kickback statute”)

It is a felony for a person or entity to knowingly or willfully solicit or receive any remuneration in return for referring an individual for the furnishing or arranging for the furnishing of any item for which payment may be made under a federal health care program, or in return for purchasing, leasing or arranging for or recommending the purchasing or leasing of any item for which payment may be made under federal health care programs. Likewise, it is a felony for a person or entity to knowingly or willfully offer or pay any remuneration to induce a person to refer a person for the furnishing or arranging for the furnishing of any item for which payment may be made under a federal health care program, or the purchase or lease or the recommendation of the purchase or lease of any item for which payment may be made under a federal health care program. These prohibitions do not apply to any amount paid by an employer to an employee.

2. Beneficiary Inducement Statute (42 U.S.C. § 1320a-7a (a)) (“inducement statute”)

This statute imposes civil monetary penalties upon a person or entity that offers or gives remuneration to any Medicare beneficiary (or beneficiary under a state health care program) that the offer or knows, or should know, is likely to influence the recipient to order an item for which payment may be made under a federal or state health care program. In the preamble to the regulations implementing this provision, the OIG stated that the statute does not prohibit the giving of incentives that are of "nominal value." The OIG defines "nominal value" as no more than $10.00 per item or $50.00 in the aggregate to any one beneficiary on an annual basis. "Nominal value" is based on the retail purchase price of the item.

3. Anti-Solicitation Statute (42 U.S.C. § 1395m(a)(17))

A supplier of a covered item may not contact a Medicare beneficiary by telephone regarding the furnishing of a covered item unless (i) the beneficiary has given written permission for the contact, or (ii) a supplier has previously provided the covered item to the beneficiary and the supplier is contacting the beneficiary regarding the covered item, or (iii) if the telephone contact is regarding the furnishing of the covered item other than an item already furnished to the beneficiary, the supplier has furnished at least one covered item to the beneficiary during the preceding fifteen months.

4. False Claims Act (31 U.S.C. § 3729)

Any person or entity who knowingly presents to a federal health care program a fraudulent claim for payment, or knowingly uses a false record or statement to obtain payment from a federal program, is subject to civil monetary penalties.

5. False, Fictitious or Fraudulent Claims (18 U.S.C. § 287)

Whoever makes or presents to any person or officer in the civil military, or naval service of the United States, or to any department or agency thereof, any claim upon or against the United States, or any department or agency thereof, knowing such claim to be false, fictitious, or fraudulent, shall be imprisoned not more than five years and shall be subject to a fine in the amount provided in this title.

6. Stark II Statute (42 U.S.C. § 1395nn)

The "Stark II" provisions of the Omnibus Budget Reconciliation Act of 1993, as amended, provide that if a physician has a financial relationship with an entity providing "designated health services," then the physician may not refer patients to the entity unless one of the statutory or regulatory exceptions applies. Designated health services include (i) durable medical equipment, (ii) parenteral and enteral nutrients, (iii) prosthetics, orthotics and prosthetic devices and supplies, and (iv) outpatient prescription drugs, among others.

B. Safe Harbors

Safe harbor regulations issued under the anti-kickback statute provide "bright line" tests defining arrangements that do not violate the statute. If a business arrangement clearly falls within a safe harbor, then it is not violative of the anti-kickback statute. If the arrangement does not clearly fall within a safe harbor, then it must be examined in light of the anti-kickback statute and related court decisions to determine if it violates the statute. Of the various safe harbors, five are particularly pertinent to suppliers.

1. Small Investment Interests

For investments in small entities, "remuneration" does not include a return on the investment if a number of standards are met, including the following: (i) no more than forty percent of the investment can be owned by persons who can generate business for or transact business with the entity, and (ii) no more than forty percent of the gross revenue may come from business generated by investors.

2. Space Rental

Remuneration does not include a lessee's payment to a lessor as long as a number of standards are met, including the following: (i) the lease agreement must be in writing and signed by the parties, (ii) the lease must specify the premises covered by the lease, (iii) if the lease gives the lessee periodic access to the premises, then it must specify exactly the schedule, the intervals, the precise length, and the exact rent for each interval, (iv) the term must be for not less than one year, and (v) the aggregate rental charge must be set in advance, be consistent with fair market value, and must not take into account business generated between the lessor and the lessee.

3. Equipment Rental

Remuneration does not include any payment by a lessee of equipment to the lessor of equipment as long as a number of standards are met, including the following: (i) the lease agreement must be in writing and signed by the parties, (ii) the lease must specify the equipment, (iii) for equipment to be leased over periods of time, the lease must specify exactly the scheduled intervals, their precise length and exact rent for each interval, (iv) the term of the lease must be for not less than one year, and (v) the rent must be set in advance, be consistent with fair market value, and must not take into account any business generated between the lessor and the lessee.

4. Personal Services and Management Contracts

Remuneration does not include any payment made to an independent contractor as long as a number of standards are met, including the following: (i) the agreement must be in writing and signed by the parties, (ii) the agreement must specify the services to be provided, (iii) if the agreement provides for services on a sporadic or part-time basis, then it must specify exactly the scheduled intervals, their precise length and the exact charge for each interval, (iv) the term of the agreement must be for not less than one year, (v) the compensation must be set in advance, be consistent with fair market value, and must not take into account any business generated between the parties, and (vi) the services performed must not involve a business arrangement that violates any state or federal law.

5. Employees

Remuneration does not include any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made, in whole or in part, under Medicare or under a state health care program.

C. OIG Advisory Opinions

A health care provider may submit to the OIG a request for an advisory opinion concerning a business arrangement that the provider has entered into or wishes to enter into in the future. In submitting the advisory opinion request, the provider must give to the OIG specific facts. In response, the OIG will issue an advisory opinion concerning whether or not there is a likelihood that the arrangement will implicate the anti-kickback statute. Although advisory opinions may not be relied on by anyone except the requesting parties, they provide valuable insight into the OIG's views on certain kinds of arrangements. Past advisory opinions are available online at http://oig.hhs.gov/fraud/advisoryopinions.html.

D. OIG Special Fraud Alerts and Special Advisory Bulletins

From time to time, the OIG publishes Special Fraud Alerts and Special Advisory Bulletins that discuss business arrangements that the OIG believes may be abusive, and educate the DME and pharmacy industries concerning fraudulent and/or abusive practices that the OIG has observed and is observing in the industry. These documents reflect the OIG's opinions regarding the application of the fraud and abuse laws. Some of the Special Fraud Alerts and Special Advisory Bulletins relevant to the supplier are the following:

1. Special Fraud Alert: Joint Venture Arrangements

The OIG's first Fraud Alert, issued in 1989, concerned joint venture arrangements between clinical laboratories, suppliers and other providers and their referral sources. In the 1980s, it was common for a supplier to enter into a partnership with a hospital or other entity to form a new supplier. The investors would invest little capital in the partnership, which would contract out substantially all of its operations to the DME investor. In the OIG's view, these ventures were not legitimate businesses, but simply mechanisms to lock up referral streams and compensate referral sources for referring business, in violation of the anti-kickback statute. The Fraud Alert included a list of "questionable features" which could suggest an anti-kickback violation. Those questionable features included selection of investors on the basis of their ability to generate referrals; an investor engaged in the same line of business as the venture and acting as a subcontractor; and disproportionately large returns on small investments.

2. Special Fraud Alert: Routine Waiver of Copayments or Deductibles Under Medicare Part B

In this Special Fraud Alert, the OIG stated that routine waiver of Medicare cost-sharing amounts "is unlawful because it results in (1) false claims, (2) violations of the anti-kickback statute, and (3) excessive utilization of items and services paid for by Medicare." It listed some "suspect marketing practices" including advertisements stating "Medicare Accepted As Payment in Full" or "No Out-Of-Pocket Expense;" routine use of "financial hardship" forms with no good faith attempt to determine the beneficiary's actual financial condition; and collection of copayments and deductibles only from beneficiaries who have Medicare supplemental insurance. Waiver of copayments is a significant issue for suppliers of high-cost DME, particularly power wheelchairs and scooters, because high copayments (approximately $1000.00 in the case of a K0011 power wheelchair) are a major disincentive to potential customers.

3. OIG's April 2003 Special Advisory Bulletin: Contractual Joint Ventures

In April 2003, the OIG published a Special Advisory Bulletin entitled "Contractual Joint Ventures." The Advisory Bulletin focuses on a situation where a health care provider in one line of business ("Owner") expands into a related line of business by contracting with an existing provider ("Manager"). The Owner's line of business is to provide new products to the Owner's existing patient base. The Manager not only manages the new line of products, but also supplies the Owner with inventory, employees, physical space, billing and other services. In essence, the Owner contracts out substantially the entire operation to the Manager and the Owner pockets the profits from this new line of business. These ventures are very similar to those described in the 1989 Special Fraud Alert, except that the supplier does not own equity in the venture.

According to the bulletin, the practical effect of the relationship between the Owner and the Manager is for the Owner to have the opportunity to bill for business that is, in reality, provided by either the Manager or by a "joint venture" formed by the Owner and Manager. According to the bulletin, the OIG looks at this type of arrangement as nothing more than a kickback, with remuneration (in form of profits retained by the Owner) flowing back to the Owner.

Therefore, if a supplier desires to open up a mail order respiratory pharmacy, then it must assume financial risk and operational responsibilities in operating the pharmacy, Likewise, if a hospital contracts with a supplier for management services for the hospital's DME operation, then while the supplier can provide certain management and administrative services, the financial risk and operational responsibilities of the DME operation must be borne by the hospital.

4. Special Fraud Alert: Rental of Space in Physician Offices by Persons or Entities to Which Physicians Refer

A number of suppliers rent space in the offices of physicians or other practitioners. The OIG is concerned that in such arrangements, the rental payments may be disguised kickbacks to the physician in violation of the anti-kickback statute. One of the specific concerns of the OIG is "consignment closet" arrangements between suppliers and physicians. It is common for suppliers to place certain items of equipment and supplies in physicians' offices for the convenience of physicians and patients. If a patient needs crutches, for example, the physician can dispense the crutches at the time of the office visit. The physician's office then informs the supplier, which bills for the crutches and replenishes the consignment closet inventory. These arrangements serve a legitimate purpose, but in the past some suppliers paid excessive amounts of rent to the physicians for the space used to store the consignment inventory, as a way of disguising payments for referrals.

The questionable features of suspect rental arrangements for space in physicians' offices may be reflected in three areas: (1) the appropriateness of rental agreements; (2) the rental amounts; and (3) time and space considerations. Separately or together, specific details of these arrangements may result in an arrangement that violates the anti-kickback statute. The Space Rental safe harbor to the anti-kickback statute can protect legitimate arrangements. Arrangements for office equipment or personal services of physicians' office staff can also be structured to comply with the Equipment Rental safe harbor and Personal Services and Management Contracts safe harbor.

5. Offering Gifts and Other Inducements to Beneficiaries

A person who offers or transfers to a Medicare or Medicaid beneficiary any remuneration that the person knows or should know is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier of Medicare or Medicaid payable items or services may be liable for civil money penalties. The statute and implementing regulations contain a limited number of exceptions.

Unless a supplier’s practices fit within an exception or are the subject of a favorable advisory opinion, any gifts or free services to beneficiaries should not exceed $10 per item and $50 annually. The OIG is considering the possibility of safe harbors for two kinds of arrangements: complimentary local transportation and government-sponsored clinical trials.

6. Medical Supplies to Nursing Facilities

Nursing facilities and their residents have become common targets for fraudulent schemes involving medical supplies. Many of the supplies and

equipment used in the care of skilled nursing facility residents are provided by the nursing facility and are considered to be included in the facility's prospective payment amount. Suppliers sometime provide these generally un-covered items to the nursing facilities, but rather than bill the facility they submit claims to Medicare Part B. The claims misrepresent that the items are medically necessary for individual beneficiaries and, therefore, are reimbursable under Part B. Facilities may not report the lack of facility billing on ordered or unordered goods because they can obtain them for "free" in this manner. In exchange for the supplier keeping the facility well-stocked with non-covered supplies or equipment, the nursing facility may give the supplier access to patients' medical records and other information needed to bill Medicare. Both the supplier and the facility may be liable for submitting false claims under criminal, civil, and administrative laws. If one purpose of providing "free" supplies to the facility is to induce the nursing facility to arrange for the procurement of items paid for by Medicare or Medicaid, both parties may also be liable under the anti-kickback statute.

Other fraudulent activities include suppliers billing for items on behalf of specific patients under Medicare Part B when the patients are in skilled nursing facilities. Also, suppliers sometimes bill for unshipped or undelivered items. The supplier, in these situations, misrepresents its entitlement to payment, as well as the eligibility and coverage of individual beneficiaries. The nursing facility may also be liable if the OIG determines that the nursing facility knew or should have known that claims being submitted were false and participated in the offense.

7. Telemarketing by Durable Medical Equipment Suppliers

The beneficiary inducement statute prohibits suppliers from making unsolicited telephone calls to Medicare beneficiaries regarding the furnishing of a covered item, except in three specific situations: (i) the beneficiary has given written permission to the supplier to make contact by telephone; (ii) the contact is regarding a covered item the supplier has already furnished the beneficiary; or (iii) the supplier has furnished at least one covered item to the beneficiary during the preceding fifteen months. The statute also specifically prohibits payment to a supplier that knowingly submits a claim generated pursuant to a prohibited telephone solicitation. Accordingly, such claims for payment are false and violators are potentially subject to criminal, civil, and administrative penalties, including exclusion from federal health care programs.

Suppliers cannot do indirectly that which they are prohibited from doing directly. A supplier is responsible for verifying that marketing activities performed by third parties with whom the supplier contracts or otherwise does business do not involve prohibited activity and that information purchased from such third parties was neither obtained, nor derived, from prohibited activity. If a claim for payment is submitted for items or services generated by a prohibited

solicitation, both the supplier and the telemarketer are potentially liable for criminal, civil, and administrative penalties for causing the filing of a false claim.

Special Fraud Alerts and Special Advisory Bulletins are available online at http://oig.hhs.gov/fraud/fraudalerts.html.

VIII. State Anti-Fraud Legal Guidelines

Most states have enacted statutes prohibiting kickbacks fee splitting, patient brokering, or self-referrals. Some statutes refer to definitions and standards found in the federal statutes while others are materially different. Some state statutes apply only when the payor is a state health care program, while other statutes apply regardless of the identity of the payor.

IX. Marketing

A. Use of Employees

It is acceptable for a provider to pay commissions, bonuses and other production-based compensation to bona fide full-time and part-time employees who market the provider's products and services. There is a specific exception to the anti-kickback statute for payments to bona fide employees. Likewise, there is an "employee" safe harbor that provides that payments to a bona fide employee do not constitute illegal remuneration in violation of the anti-kickback statute. The reasoning behind this exception and safe harbor is that an employer has the duty to train, control and supervise its employees. In addition, under the doctrine of respondent superior, an employer is liable for the acts of its employees that are conducted within the course and scope of the employees' employment. As a result, the employer is motivated to exercise control over its marketing employees.

It is critical that the employee be a "bona fide" employee as opposed to being a "sham" employee. The IRS has published a laundry list of factors that define whether a person is an employee or an independent contractor. It is important that the employment relationship meet most of the IRS factors. In scrutinizing whether a person is an employee versus an independent contractor, the government (e.g., the Department of Justice and the OIG) will look at "substance over form." For example, if a provider has a written employment agreement with a person, withholds taxes and Social Security from the person's paycheck, and issues a W 2 to the person, such factors by themselves do not establish an employment relationship. Other important factors are whether the employer is supervising, training and controlling the employee. Therefore, if the provider calls a person an employee and pays the person as if he or she is an employee, but otherwise treats the employee as if he or she is an independent contractor, then the government will likely conclude that the person is an independent contractor.

If a provider pays commissions, bonuses and other production-based compensation to an independent contractor to market for the provider, then the anti-kickback statute will likely be violated. The only possible mechanism for a provider to

pay an independent contractor (a person who receives a 1099) for marketing is for the provider to pay a fixed annual fee to the contractor that is the fair market value equivalent of the person's efforts, not his or her results. In other words, the relationship with the independent contractor needs to fall within the guidelines of the Personal Services and Management Contracts safe harbor.

B. Use of Independent Contractors

As discussed above, a provider cannot pay commissions, bonuses or other production-based payments to independent contractors for marketing. To do so would violate the anti-kickback statute. The only mechanism to pay an independent contractor for marketing services is to fit (or substantially fit) the relationship within the Personal Services and Management Contracts safe harbor. Among other requirements, payment to the independent contractor must be fixed one year in advance and must be the fair market value equivalent of the contractor's services.

C. Media Advertising

It is acceptable for the provider to advertise on television, on radio, in the newspaper and in other media outlets.

D. Approaching Physicians and Other Referral Sources

It is acceptable for the provider to call on physicians, hospital discharge planners, home health agencies, and other referral sources in order to market the provider’s products and services. In so doing, the provider can hand out brochures and other promotional literature. The provider cannot, however, directly or indirectly give something of value to the referral sources for referrals.

E. Mail-Outs

On condition that the provider secures a mailing list in such a way that HIPAA is not violated (e.g., the list comes from a non-covered entity, then the provider can mail out promotional literature to the individuals on the list. In so doing, the provider can include a stamped, self-addressed postcard. In the promotional literature, the provider can ask the recipient to sign and mail the postcard to the provider, which will then give the provider the right to call the recipient.

F. Promotional Items to Customers and Potential Customers

The provider can offer an item of nominal value (i.e., retail value of not more than $10) to customers and prospective customers. For example, the provider can run ad in the newspaper that encourages individuals to visit the provider; the ad can say that all visitors will receive a coffee mug (that has a retail value of $7.99).

G. Health Fairs, Luncheons and Kiosks

The provider can participate in local health fairs. In so doing, it can set up a table or booth and give away items with a retail value of not more than $10. Similarly, the provider can put on a short program during lunch at a senior citizens' center, at which time the provider can distribute promotional literature. The provider can place a kiosk in a mall that promotes the provider's products and services.

X. Business Arrangement Between HME Company and Pharmacy

A. Historical Overview

In the early 1990s, many HME companies and pharmacies collaborated to provided products and services to their customers. The respiratory field is a prime example. A local HME company would sell nebulizers and other respiratory equipment to customers. These customers needed respiratory medications, such as albuterol sulfate, to use with their nebulizers but the HME company could not dispense these medications. As a result, the HME company would enter into a relationship with a pharmacy whereby the pharmacy would dispense the respiratory medications directly to the customers, the HME company would pay the pharmacy a wholesale price for the medications, and the HME company would then bill the Medicare carrier. These “wholesale” arrangements came to an end on December 1, 1996, when HCFA (now CMS) decreed that only licensed pharmacies could be reimbursed for Medicare-covered prescription medications.

Another common type of arrangement between HME companies and pharmacies was the “fee-for-service” arrangement. Under this type of arrangement, the HME company would refer its nebulizer customers to a pharmacy, the pharmacy would dispense the respiratory medications to the customers, and the pharmacy would bill the Medicare carrier. The pharmacy would then pay compensation to the HME company for services rendered to the customers. This type of arrangement was attacked by the government as being a violation of the Medicare anti-kickback statute. Such arrangements must be avoided.

Since the government strictly scrutinizes arrangements between providers where at least one of the providers is a referral source, it is important that providers carefully consider the risks involved in any HME/pharmacy business arrangement.

B. Business Arrangements That Meet Legal Guidelines

1. Joint Venture

The government may carefully scrutinize a joint venture between providers in order to ensure that the venture is not merely a sham whereby one entity is paying remuneration to the other entity in exchange for the referral of customers.

The safe harbor applicable to joint ventures is the Small Investment Interest safe harbor, which requires that (i) no more than 40% of the investment may be owned by persons who can generate business for or transact business with the entity; and (ii) no more than 40% of the gross revenue may come from business generated by the investors. This is knows as the "60-40" rule.

It is rare that a joint venture will fit within the Small Investment Interest safe harbor because it is difficult to meet the "60-40" rule. If the Small Investment Interest safe harbor is not met, then the government will examine the joint venture under the "one purpose" test. The basic inquiry under this test is whether one purpose of the arrangement is to induce referrals. In deciding whether to exercise its discretion to bring an enforcement action against the parties to a joint venture, the government will look to see whether the venture complies with the guidelines of the OIG's 1989 Special Fraud Alert.

2. Pharmacy Staffing Services Agreement ("PSSA")

HME companies often open their own closed-door pharmacies to dispense respiratory medications to their respiratory equipment customers. The HME company can open its closed-door pharmacy on its existing premises. However, an alternative is the PSSA. Under the PSSA, a staffing services company ("SSC") will provide a building that can house one or more smaller pharmacies owned by one or more HME companies. The HME company will obtain a state pharmacy license and a Medicare supplier number for the physical location of the HME company's new pharmacy. The SSC will provide specifically defined staffing services to the HME company's pharmacy. The PSSA needs to adhere to the guidelines set out in the OIG's April 2003 Special Advisory Bulletin entitled "Contractual Joint Ventures" described above.

3. Operational Services

A pharmacy and HME company can offer services to each other. The company that receives the services must pay fair market value for the services and, in order to reduce the risk of government scrutiny, it must fall within one of the safe harbors. These services include billing; pickup and delivery of equipment; equipment maintenance; accounting; and establishing quality control and outcome determination programs.

4. Cooperative Marketing Program

An HME company and pharmacy may enter into a cooperative marketing program. The costs and expenses of the program must be proportionately shared by the HME company and pharmacy. This type of arrangement allows an independent HME company and pharmacy to offer the same type of combined services that a national HME company/pharmacy can offer. The cooperative

marketing program offers “one stop shopping” to customers. Examples of cooperative marketing programs are:

a. Joint advertisements in the media.

b. A brochure jointly prepared by the HME company and pharmacy that promotes the products and services of both entities.

c. References to the cooperative arrangement on the letterhead and business cards of each entity.

d. A link on each entity’s website to the other entity’s website.

e. A display table that educates customers about the services offered by each entity.

f. Written information explaining the joint services offered by each entity that is inserted with the prescription medications dispensed by the pharmacy.

XI. Business Arrangement Between Pharmacy and Hospital

A. Joint Venture

Note the prior discussion in the preceding section. A pharmacy can enter into a joint venture with a hospital. In so doing, assuming that the terms of the Small Investment Interest safe harbor cannot be met, then the arrangement must comply with the OIG's 1989 Special Fraud Alert.

B. Administrative Services Agreement (“ASA”)

Increasingly, hospitals are opening up outpatient pharmacies, located on hospital premises or at a location leased or owned by the hospital. In so doing, hospitals are contracting with existing pharmacies to provide administrative services. If a pharmacy enters into an ASA with a hospital, then it is critical that the agreement comply with the guidance set out in the OIG's April 2003 Special Advisory Bulletin entitled "Contractual Joint Ventures."

C. Operational Services

A pharmacy can offer services to a hospital and vice versa. The entity that receives the services must pay fair market value for the services and, in order to reduce the risk of government scrutiny, it must fall within one of the safe harbors.

D. Cooperative Marketing Program

A pharmacy may enter into a cooperative marketing program with a hospital. The costs and expenses of the program must be proportionately shared by the parties. Examples of cooperative marketing programs are:

1. Joint advertisements in the media.

2. A brochure jointly prepared by the pharmacy and the hospital that promotes the products and services of the entities.

3. A link on each entity's website to the other entity's website.

4. A display table that educates customers about the services offered by each entity.

5. Written information explaining the joint services offered by each entity that is inserted with the prescription medications dispensed by the pharmacy.

E. Loan/Consignment Closets (applicable to HME companies)

An HME company may place inventory in the office of a physician or on the premises of a hospital. The inventory must be for the convenience only of the physician's or hospital's patients and the physician or hospital cannot financially benefit, directly or indirectly, from the inventory. It is important that the physician and hospital ensure patient choice. Technically, the HME provider can pay rent to the hospital or physician so long as the rental agreement complies with the Space Rental safe harbor. However, from a practical standpoint, because the physical space utilized by the placement of the inventory is so small, it is preferable for the HME company to pay no rent to the physician or hospital.

F. Preferred Provider Agreement ("PPA") (applicable to HME companies)

The HME company can enter into a PPA with a hospital whereby, subject to patient choice, the hospital will recommend the HME company to its patients who are about to be discharged.

XII. Relationship Between Pharmacy and Physician

A. Medical Director Agreement

A pharmacy can enter into an independent contractor Medical Director Agreement ("MDA") with a physician, even if the physician is a referral source. The MDA must comply with the (i) Personal Services and Management Contracts safe harbor and (ii) the Personal Services exception to Stark II. Among other requirements:

1. The MDA must be in writing and must have a term of at least one year.

2. The compensation to the physician must be fixed a year in advance and it must be the fair market equivalent of the actual services rendered.

3. The physician must render actual, necessary and substantive services to the pharmacy.

4. The compensation paid by the pharmacy to the physician must bear no resemblance to referrals by the physician.

B. Joint Venture in Rural Area

A pharmacy and a physician can jointly own a pharmacy if substantially (i.e., 75%) all of the business is provided to customers residing in rural areas. A "rural area" is any area outside a Metropolitan Statistical Area.

XIII. Related Issues

A. Marketing Restrictions Under HIPAA

Under HIPAA, a provider cannot allow another Covered Entity to utilize the provider's customer list for the other Covered Entity to market its products and services. However, the provider can mail materials to its own customers that educate the customers about products and services offered by the provider.

B. Compounding of Prescription Drugs

A pharmacy has the right to compound a prescription drug on condition that a number of requirements are met, one of which is that the prescription drug cannot be otherwise commercially available. The compounding practices of a pharmacy are regulated by the state's board of pharmacy. As a general rule, the FDA will not attempt to regulate pharmacies. However, if, in the FDA's eyes, a pharmacy crosses the line to manufacturing, or compounds drugs that are otherwise commercially available, then the FDA will exercise its enforcement discretion and assert jurisdiction over the pharmacy.

C. Preparing for an NSC Site Visit

Over the past year, the NSC has become aggressive in conducting unannounced site visits to ascertain if the supplier is in compliance with the 21 Supplier Standards. If the NSC concludes that the supplier is not meeting one or more standards, then the NSC will send the supplier a letter notifying it that its supplier number will be revoked in 14 days. Sometimes, revocation can be avoided if the supplier furnishes documentation within the 14 day period showing that the Supplier Standards are being met. However, if the supplier number is revoked, then the supplier must go through the appeal process, which can take 60 days. Set forth below are the basic issues that will be addressed by the

NSC in an inspection and information regarding the documentation that a supplier should provide the site inspector in order to pass the inspection.

There are several areas targeted during an NSC inspection. First, the NSC has taken a very aggressive approach concerning supplier compliance with Supplier Standard number four. This standard requires that a supplier:

> fills orders, fabricates, or fits items from its own inventory or by contracting with other companies for the purchase of items necessary to fill the order. If it does, it must provide, upon request, copies of contracts or other documentation showing compliance with this standard.

On its face, this standard clearly requires only that a supplier provide items to beneficiaries from its own inventory. However, the NSC has increasingly been citing suppliers for failure to have adequate inventory to meet the needs of its beneficiaries. Despite many requests of the NSC and CMS to clarify what constitutes adequate inventory, no standard has yet been offered that would assist suppliers in complying with this Supplier Standard. This ambiguity has resulted in Supplier Standard number four being cited by the NSC as the reason for revocation of a supplier's number.

Since a supplier cannot know what constitutes sufficient inventory for the NSC, it is a good policy for all suppliers to enter into a written agreement with their distributors stating that the supplier is authorized to purchase equipment from the distributor. The agreement should state the credit limit available to the supplier and indicate the terms on which the supplier may purchase and receive items from the distributor. The agreement should be designed to meet the requirement that suppliers "contract with other companies for the purchase of items necessary to fill the orders" and should be signed by both parties.

In addition to inventory requirements, suppliers are facing increased scrutiny regarding the status and adequacy of their insurance policies. The NSC will attempt to contact the insurance underwriter to verify that the supplier's insurance coverage is current. If the NSC is told that the insurance is not current or if the underwriter does not respond to the NSC request, this will be used as a reason for revocation of the supplier number. In order to avoid this situation, suppliers should request that their local agent call to verify coverage with the underwriter on a routine basis. The supplier should also verify that it is the underwriter's policy to provide information to governmental agencies that are contacting the underwriter to verify coverage. Also, effective August, 2004, all suppliers will be required to list the NSC as a "Certificate Holder" on their insurance policy.

Finally, the NSC is increasingly using Supplier Standard number one as a basis for revocation of supplier number. This standard requires that a supplier "operates its business and furnishes Medicare covered items in compliance with all applicable federal and state licensure and regulatory requirements." The NSC has begun routinely revoking supplier numbers for violation of this standard if the supplier has failed to maintain or

adequately document its compliance with a state's regulatory requirements. These would include any state requirement requiring licensure or certification for individuals who fit diabetic shoes, or that a company must have a bedding license to provide hospital bedding to its beneficiaries.

Given the increased scrutiny that suppliers face from the NSC regarding compliance with the Supplier Standards, it is a good idea for suppliers to maintain an NSC notebook that contains all the information necessary to verify compliance with the standards. At a minimum, the notebook should contain the following:

- A copy of all state and federal licenses and certificates required to conduct business (the licenses should accurately reflect the location's address);

- A copy of the supplier's original 855S and its most recent re-enrollment;

- A copy of the supplier's contracts with its wholesalers, signed by both parties, that provide, at a minimum:

    - That the supplier is entitled to purchase materials from the wholesaler;

    - That the supplier's account is in good standing; and

    - That states the credit limit established between the supplier and wholesaler.

- A sample of the purchase option form provided to patients who are renting capped rental equipment;

- A copy of the warranty information for any items supplied to beneficiaries upon delivery of their equipment or supplies;

- A copy of the supplier's entire liability insurance policy covering the supplier's place of business (the physical location must be listed as a covered location);

- A sample copy of forms maintained by the supplier that show proof of delivery of items supplied;

- A copy of any service contracts that the supplier has with any third party to provide service on Medicare covered items rented to beneficiaries;

- A sample copy of the supplier standards given to beneficiaries to whom the supplier provides Medicare covered items;

- A copy of the supplier's complaint resolution protocol used to address beneficiary complaints. This form must include:

    - The name, address, telephone number, and health insurance claim number of the beneficiary;

    - A summary of the complaint; and

    - Any actions taken to resolve the complaint.

  In addition to these documents, a supplier should be prepared to provide evidence of compliance with the following:

- Evidence that its physical location is handicapped accessible;

- As a general rule, two or more Medicare suppliers cannot be located in the same physical location. Inspectors may quiz the supplier about any similar businesses in the same location that have a Medicare supplier number;

- Suppliers must post reasonable business hours and must be available for inspection by CMS during these hours;

- Suppliers must maintain a primary business telephone number that must be listed in a local or toll free directory under its business name; and

- Suppliers must have sufficient inventory on hand (if inventory is off-site at a warehouse, advise the inspector of this and offer the inspector the opportunity to view the warehouse).

These are the primary issues the NSC has focused on during recent inspections. By maintaining a notebook containing the appropriate documentation, a supplier can avoid failing a site inspection.
