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Executive Director and
Director of Education

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October 20, 1999

The Honorable John R. McGinley, Jr.
Chairman
Independent Regulatory Review Commission
14th Floor, Harristown 2
333 Market Street
Harrisburg, PA 17101

SUBJECT: Regulation 14-459
Department of Public Welfare
Omnibus Medicaid Pharmaceutical Service Regulations

Dear Chairman McGinley:

On behalf of the over 3,000 members of the Pennsylvania Pharmacists Association, I would like to respectfully offer the following comments and objections to Regulation 14-459 of the Department of Public Welfare which makes "omnibus" revisions to the Department's Medicaid pharmaceutical services rules.

Omission of Notice of Proposed Rulemaking

As noted by the Health Law Project in its October 4, 1999 objections to Regulation 14-459, we object to the adoption of these regulations without the publication of a Notice of Proposed Rulemaking and without prior review of the regulations by the Department's Medical Assistance Advisory Committee. There is no emergency or extraordinary set of circumstances, which justifies the omission of notice of proposed rulemaking and consultation with the MAAC. In fact, in most cases the Department has been aware of the need to adopt regulations similar to those contained in this package for many years. The public interest is best served by ensuring a full and complete opportunity for public review and comment concerning these regulations.

Although we understand the Commission's historical reluctance to review procedural issues of this type, we believe that it would be appropriate for the Commission to apply a more rigorous standard of scrutiny to regulations adopted in a manner which minimizes the opportunities for public participation and comment.

List of Drugs Eligible for Reimbursement

The Department has proposed to reenact at Section 1121.54(1) a requirement currently found at Section 1121.54(24) which provides that pharmacies are responsible for checking the list of drugs eligible for reimbursement by virtue of either being subject to or exempt from the National Rebate Agreement with the federal Health Care Financing Administration.

The list of drugs eligible for reimbursement covers thousands of drugs and is subject to modification on almost a weekly basis. In Practice, pharmacies do not review the list of covered drugs, but instead enter prescriptions upon receipt into the Department's on-line computerized claims adjudication system. Pharmacies are then immediately advised by the Department if a drug is not eligible for reimbursement by virtue of neither being covered by nor exempt from the National Rebate Agreement. Pharmacies utilizing the Department's on-line claims adjudication system should be entitled to rely upon the Department's determination regarding whether drugs are eligible for reimbursement and should not be required to engage in time consuming and duplicative manual checks of lists of covered drugs. Accordingly, we recommend deleting the last sentence of Section 1121.54(1).

Special Requirements for Dispensing Weight Control and Fertility Drugs

The Department has recommended modification of Section 1121.54(3) to only authorize payment for obesity, anorexia, weight loss, appetite control or fertility drugs when the drugs have been approved and prescribed for another medically accepted indication and the appropriate indication, use or diagnosis appears on the original prescription in the prescriber's handwriting.

Pharmacies are generally not able to independently verify whether a prescribed indication, use or diagnosis for a drug has been approved by the FDA. To the extent a physician prescribes an obesity, anorexia, weight loss, appetite control of fertility drug and certifies that it has been prescribed for another proper indication, use or diagnosis, payment should be authorized to the pharmacy dispensing the medication. To the extent any recoupment of payment wrongfully made occurs, the recoupment should be from the prescribing physician, not the pharmacy.

In addition, the requirement that the approved indication, use or diagnosis is properly certified by the physician, no rational purpose is served by requiring a handwritten certification. A telefaxed, telephone or computerized certification should be sufficient, provided that appropriate documentation of the certification is maintained.

In light of the severe health consequences associated with morbid obesity and anorexia, the members of PPA also question the continued rationality of disallowing any reimbursement for the treatment of obesity and anorexia. Instead, we recommend allowing reimbursement for these drugs in appropriate circumstances subject to a prior authorization requirement.

Prescriptions From Barred or Suspended Physicians

The Department has proposed to reenact a requirement currently set forth in Section 1121.54(18), which prohibits pharmacies from receiving payments for items prescribed by prescribers barred or suspended from participating in the Medicaid Program. The regulations provide that the Department "will periodically send pharmacies a list of names of such prescribers" and declare that "pharmacies are responsible for checking this list before filling prescriptions."

Pharmacies are currently required to enter into the Department's on-line computerized claims adjudication system the name and license number of each prescriber. After submitting this information to the Department, pharmacies are immediately advised whether a prescriber is ineligible to participate in the Medicaid Program. To the extent pharmacies utilize the Department's on-line claims adjudication system, pharmacies should be entitled to rely upon the determinations made by

the Department without the time consuming and duplicative requirement to independently checking manual lists of barred or suspended prescribers.

Other Issues

In addition to the issues listed above, we also respectfully recommend that the Commission carefully consider the recommendations offered on October 4, 1999 by the Pennsylvania Health Law Project. The questions posed in the Health Law Project's October 4, correspondence regarding the scope and extent of benefits available to Medicaid recipients deserve careful review and consideration.

Please do not hesitate to contact me if you have any questions regarding these recommendations.

Sincerely,

Carmen A. DiCello, R.Ph.
Executive Director

CAD/TKL

cc: Senate Committee on Public Health and Welfare
House Committee on Health and Human Services

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Attorneys for the Consumer
Subcommittee of the MAAC

FOR YOUR INFORMATION
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Executive Director - PPA
508 North Third Street
Harrisburg, PA 17101

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Section 1121.54 - Noncovered services and items.

1. **The exception for drugs that are not on the rebate program is erroneously described.**

   A. This is misleading and inappropriate. Section 1121.54 (1)'s allows the Department to pay for a drug that is not on the national rebate program where the drug is "authorized by the federal government as essential to the health of a medical assistance recipient." This phrasing is contrary to the language of OBRA and is misleading. OBRA '90 authorizes States to pay for drugs outside the rebate program where: (i) the State determines that the availability of the drug is essential to the health of beneficiaries; (ii) such a drug as been given a rating of 1-A by the FDA; and (iii) the physician has obtained prior authorization. Under OBRA it is for the state and not the federal government to decide which drugs should and could be available, even though not on the rebate program, but because essential to the health of beneficiaries. Here, the Department of Public Welfare unilaterally decided which drugs shall be available to Pennsylvanians, even though not on the federal rebate program. The Department did this without public input or guidance from the General Assembly or the Medical Assistance Advisory Committee.

   B. The Department should employ the medical necessity standards elsewhere employed throughout the Medical Assistance provisions. As it is for the state to decide which drugs should be available to MA recipients, even though not on the federal rebate program, because essential to the health of the recipients, the state should utilize the medical necessity terminology. Accordingly, any drug that is not on the rebate program but which is medically necessary for the patient, should be made available and covered under this provision.

2. The regulations employ a new term "medically accepted indication" but, this term must be defined in the definitions section of the regulation.

A. Terms of art must be fully and adequately defined in order to prevent confusion and unnecessary complications. Throughout the regulations, the Department uses this "medically accepted indication" term with no indication of what is meant. For example, where a doctor prescribes an otherwise covered legend or nonlegend drug for a use that is not for a medically accepted indication this prescription is not covered. In 42 U.S.C. §1396r-8(k)(6), Congress defines "medically accepted indication" as "any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act, which appears in peer-reviewed medical literature or which is accepted by one of more of the following compendia: the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, and the United States Pharmacopeia-Drug Information." The Definitions section of the regulations, 55 Pa. Code §1121.2, must be amended to include this definition.

B. It is unnecessarily confusing that the regulations vary between use of "medically accepted indication" and "medically acceptable indication". OBRA '90 employs the term "medically accepted indication". Interspersing a different term suggests that there are multiple standards. The Department should use "medically accepted indication" only.

3. The exclusion of coverage for prescriptions in Section 1121.54(5) is inherently unfair to consumers, excessively broad, and not in accordance with relevant requirements of federal law.

A. The exclusion from coverage of entire classes of drugs is bad health care policy. OBRA 1990 permits states to exclude from coverage or otherwise restrict agents when used for anorexia or weight gain, to promote fertility, for cosmetic purposes or hair growth, for the symptomatic relief of cough and colds, and for smoking cessation. The Department has unilaterally elected to prohibit all of these, with minor exception and without any public comment whatsoever.

1) Without guidance or instruction from the General Assembly or the Medical Assistance Advisory Committee, the Department has taken it upon itself to exclude from coverage all drugs for symptomatic relief of cough or colds, except when prescribed for MA recipients under 21 years of age or for nursing home residents. This prescription defies logic. There is no sound basis for preventing alleviation of symptoms, which may well return people to work sooner, save the Medical

Assistance Program money, etc. This entire class of drugs should not be excluded. At a minimum, exceptions must be made for circumstances in which the prescription of such drugs is medically necessary.

2) Smoking cessation should no longer be excluded from coverage. Clearly, a state that thought it imperative to go after and obtain compensation from the tobacco industry for the state monies paid in the Medical Assistance Program for health care costs related to tobacco use should not be precluding access to drugs for nicotine cessation. At a minimum, exceptions must be made for circumstances in which the prescription of such drugs is medically necessary. Because there is no sound basis for excluding coverage where inclusion would save the Medical Assistance program money, this entire class of drugs should not be excluded.

B. EPSDT requirements are violated by the draft regulations.

1) The restrictions do not comport with federal law. EPSDT requires that children under the age of 21 receive any and all medical services deemed medically necessary. Where the prescription of any drug from one of these restricted drugs classes is medically necessary for a child under 21, the state must cover that prescribed drug. The draft regulations ignore federal EPSDT coverage requirements.

C. The regulations must define exactly what drugs and classes of drugs will not be covered. In 1121.54(3)(iii), the Department excludes from coverage pharmaceuticals relating to hair growth or "other cosmetic purposes". The authors of these comments have no idea what is intended by "other cosmetic purposes". This is a broad exclusion that is subject to many differing interpretations by plans and providers if not properly defined.

D. The exclusion of drugs that promote fertility is broad and undefined. 62 P.S. 443.6(f) prohibits the department from covering any medical services, procedures, or drugs related to infertility therapy. This phrasing places the focus on the purpose of the prescription. The regulations exclude from coverage drugs used, prescribed, or indicated to promote fertility unless the drug is prescribed for any medically accepted indication other than treating infertility and this appears on the original prescription in the prescriber's handwriting. The second part of this exception is unfairly burdensome to the consumer. The Department must allow the pharmacist to call the doctor to verify a non-fertility related purpose of the prescription. Then the pharmacist may write on the prescription the non-fertility related purpose that the doctor

omitted. The Department should not bar the consumer's reimbursement or prevent the consumer's prescription access because of a prescriber's failure to include on a prescription that which prescribers may not know to include on a prescription. This should be changed.

Section 1126.54 - Noncompensable services and items for Ambulatory Surgical Center Services/Short Procedure Unit Services.

1. Section 1126.54(17) fails to be consistent with the rest of the regulations thus allowing confusion and broadening, by omission, the proscription of this section.

   A. The regulations omit important language and, consequently, are unacceptably broad. As written, the regulations prohibit coverage for any medical service, procedure, or pharmaceuticals related to infertility, including surrogacy services. This language is impermissibly broad. 62 P.S. 445.1 only prohibits coverage related to infertility therapy. The statutory language clearly implies the purpose of the services being proscribed as those which are used for treating infertility. Sections 1121.64(3)(v), 1129.56, 1141.59 (18), and 1163.59 all utilize the terms "infertility therapy" or "for treating infertility". The language of the regulatory section expands far beyond the statutory proscription to reach anything related to infertility. This must be changed to reflect the intent of the General Assembly and to comport with all other sections of the regulation.

   B. If not revised, this section, as written, will invite confusion and varying interpretations. As written the regulation leaves up for grabs exactly who is to decide whether services are related to infertility and how they are to decide this. This is dangerous, especially where treatment is medically necessary for treatment of something other than infertility but the services can, in some ways be construed as related to infertility.

Section 1126.54 (Noncompensable services and items for Ambulatory Surgical Center Services/Short Procedure Unit Services), 1129.56 (Noncompensable services and items for Rural Health Clinic Services), 1141.59 (Noncompensable services and items for Physician Services), 1163.59 (Noncompensable services and items for Inpatient Hospital Services)

1. These sections' use of the words "related to" and failure to make exception for medically necessary services or procedures are improper and excessively broad.

A. These regulations are unacceptably broad. These regulations prohibit coverage for medical services, procedure, or pharmaceuticals related to treating infertility (or infertility therapy). The use of the words "related to" open up a multitude of unintended limitations that can be added to what should be a specific proscription. The General Assembly intended to prohibit coverage for services prescribed for the purpose of treating infertility. The broad drafting of these regulations allows for many varied interpretations. Who is to decide whether services are "related to" treating infertility and how are they to decide this? Leaving such factors entirely up in the air is not appropriate and is dangerous, especially where treatment is medically necessary for something other than infertility but the services can, in some ways be construed as related to infertility.

B. These regulations fail to allow for medically necessary services. In reaching beyond their permissible reach, these sections fail to make exception for medically necessary services or procedures. There are medically necessary services, procedures, or pharmaceuticals that might conceivably be construed as related to treating a patient's infertility but which actually prescribed for another medically significant condition. Examples might include screening, diagnosis, and treatment for reproductive maladies such as ovarian or cervical cancer, prostate cancer, or testicular cancer. These sections, as written, are too broad.

2. The Department fails to include the word "therapy", thus making this section inconsistent with the rest of the regulation. 1126.54(a)(17) should read "Any medical services, procedures, or pharmaceuticals related to infertility therapy, including surrogacy services."

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Section 1121.54 - Noncovered services and items.

1. The exception for drugs that are not on the rebate program is erroneously described.

   A. **This is misleading and inappropriate.** Section 1121.54 (1)'s allows the Department to pay for a drug that is not on the national rebate program where the drug is "authorized by the federal government as essential to the health of a medical assistance recipient." This phrasing is contrary to the language of OBRA and is misleading. OBRA '90 authorizes States to pay for drugs outside the rebate program where: (i) the State determines that the availability of the drug is essential to the health of beneficiaries; (ii) such a drug as been given a rating of 1-A by the FDA; and (iii) the physician has obtained prior authorization. Under OBRA it is for the state and not the federal government to decide which drugs should and could be available, even though not on the rebate program, but because essential to the health of beneficiaries. Here, the Department of Public Welfare unilaterally decided which drugs shall be available to Pennsylvanians, even though not on the federal rebate program. The Department did this without public input or guidance from the General Assembly or the Medical Assistance Advisory Committee.

   B. **The Department should employ the medical necessity standards elsewhere employed throughout the Medical Assistance provisions.** As it is for the state to decide which drugs should be available to MA recipients, even though not on the federal rebate program, because essential to the health of the recipients, the state should utilize the medical necessity terminology. Accordingly, any drug that is not on the rebate program but which is medically necessary for the patient, should be made available and covered under this provision.

2. The regulations employ a new term "medically accepted indication" but, this term must be defined in the definitions section of the regulation.

A. **Terms of art must be fully and adequately defined in order to prevent confusion and unnecessary complications.** Throughout the regulations, the Department uses this "medically accepted indication" term with no indication of what is meant. For example, where a doctor prescribes an otherwise covered legend or nonlegend drug for a use that is not for a medically accepted indication this prescription is not covered. In 42 U.S.C. §1396r-8(k)(6), Congress defines "medically accepted indication" as "any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act, which appears in peer-reviewed medical literature or which is accepted by one of more of the following compendia: the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, and the United States Pharmacopeia-Drug Information." The Definitions section of the regulations, 55 Pa. Code §1121.2, must be amended to include this definition.

B. **It is unnecessarily confusing that the regulations vary between use of "medically accepted indication" and "medically acceptable indication".** OBRA '90 employs the term "medically accepted indication". Interspersing a different term suggests that there are multiple standards. The Department should use "medically accepted indication" only.

3. The exclusion of coverage for prescriptions in Section 1121.54(3) is inherently unfair to consumers, excessively broad, and not in accordance with relevant requirements of federal law.

A. **The exclusion from coverage of entire classes of drugs is bad health care policy.** OBRA 1990 permits states to exclude from coverage or otherwise restrict agents when used for anorexia or weight gain, to promote fertility, for cosmetic purposes or hair growth, for the symptomatic relief of cough and colds, and for smoking cessation. The Department has unilaterally elected to prohibit all of these, with minor exception and without any public comment whatsoever.

1) **Without guidance or instruction from the General Assembly or the Medical Assistance Advisory Committee, the Department has taken it upon itself to exclude from coverage all drugs for symptomatic relief of cough or colds, except when prescribed for MA recipients under 21 years of age or for nursing home residents.** This proscription defies logic. There is no sound basis for preventing alleviation of symptoms, which may well return people to work sooner, save the Medical

Assistance Program money, etc. This entire class of drugs should not be excluded. At a minimum, exceptions must be made for circumstances in which the prescription of such drugs is medically necessary.

2) **Smoking cessation should no longer be excluded from coverage.** Clearly, a state that thought it imperative to go after and obtain compensation from the tobacco industry for the state monies paid in the Medical Assistance Program for health care costs related to tobacco use should not be precluding access to drugs for nicotine cessation. At a minimum, exceptions must be made for circumstances in which the prescription of such drugs is medically necessary. Because there is no sound basis for excluding coverage where inclusion would save the Medical Assistance program money, this entire class of drugs should not be excluded.

B. **EPSDT requirements are violated by the draft regulations.**

1) **The restrictions do not comport with federal law.** EPSDT requires that children under the age of 21 receive any and all medical services deemed medically necessary. Where the prescription of any drug from one of these restricted drugs classes is medically necessary for a child under 21, the state must cover that prescribed drug. The draft regulations ignore federal EPSDT coverage requirements.

C. **The regulations must define exactly what drugs and classes of drugs will not be covered.** In 1121.54(3)(iii), the Department excludes from coverage pharmaceuticals relating to hair growth or "other cosmetic purposes". The authors of these comments have no idea what is intended by "other cosmetic purposes". This is a broad exclusion that is subject to many differing interpretations by plans and providers if not properly defined.

D. **The exclusion of drugs that promote fertility is broad and undefined.** 62 P.S. 443.6(f) prohibits the department from covering any medical services, procedures, or drugs related to infertility therapy. This phrasing places the focus on the purpose of the prescription. The regulations exclude from coverage drugs used, prescribed, or indicated to promote fertility unless the drug is prescribed for any medically accepted indication other than treating infertility and this appears on the original prescription in the prescriber's handwriting. The second part of this exception is unfairly burdensome to the consumer. The Department must allow the pharmacist to call the doctor to verify a non-fertility related purpose of the prescription. Then the pharmacist may write on the prescription the non-fertility related purpose that the doctor

omitted. The Department should not bar the consumer's reimbursement or prevent the consumer's prescription access because of a prescriber's failure to include on a prescription that which prescribers may not know to include on a prescription. This should be changed.

Section 1126.54 - Noncompensable services and items for Ambulatory Surgical Center Services/Short Procedure Unit Services.

1. Section 1126.54(17) fails to be consistent with the rest of the regulations thus allowing confusion and broadening, by omission, the proscription of this section.

   A. **The regulations omit important language and, consequently, are unacceptably broad.** As written, the regulations prohibit coverage for any medical service, procedure, or pharmaceuticals related to infertility, including surrogacy services. This language is impermissibly broad. 62 P.S. 443.1 only prohibits coverage related to infertility therapy. The statutory language clearly implies the purpose of the services being proscribed as those which are used for treating infertility. Sections 1121.64(3)(v), 1129.56, 1141.59 (18), and 1163.59 all utilize the terms "infertility therapy" or "for treating infertility". The language of the regulatory section expands far beyond the statutory proscription to reach anything related to infertility. This must be changed to reflect the intent of the General Assembly and to comport with all other sections of the regulation.

   B. **If not revised, this section, as written, will invite confusion and varying interpretations.** As written the regulation leaves up for grabs exactly who is to decide whether services are related to infertility and how they are to decide this. This is dangerous, especially where treatment is medically necessary for treatment of something other than infertility but the services can, in some ways be construed as related to infertility.

Section 1126.54 (Noncompensable services and items for Ambulatory Surgical Center Services/Short Procedure Unit Services), 1129.56 (Noncompensable services and items for Rural Health Clinic Services), 1141.59 (Noncompensable services and items for Physician Services), 1163.59 (Noncompensable services and items for Inpatient Hospital Services)

1. These sections' use of the words "related to" and failure to make exception for medically necessary services or procedures are improper and excessively broad.

A. **These regulations are unacceptably broad.** These regulations prohibit coverage for medical services, procedure, or pharmaceuticals related to treating infertility (or infertility therapy). The use of the words "related to" open up a multitude of unintended limitations that can be added to what should be a specific proscription. The General Assembly intended to prohibit coverage for services prescribed for the purpose of treating infertility. The broad drafting of these regulations allows for many varied interpretations. Who is to decide whether services are "related to" treating infertility and how are they to decide this? Leaving such factors entirely up in the air is not appropriate and is dangerous, especially where treatment is medically necessary for something other than infertility but the services can, in some ways be construed as related to infertility.

B. **These regulations fail to allow for medically necessary services.** In reaching beyond their permissible reach, these sections fail to make exception for medically necessary services or procedures. There are medically necessary services, procedures, or pharmaceuticals that might conceivably be construed as related to treating a patient's infertility but which actually prescribed for another medically significant condition. Examples might, include screening, diagnosis, and treatment for reproductive maladies such as ovarian or cervical cancer, prostate cancer, or testicular cancer. These sections, as written, are too broad.

2. The Department fails to include the word "therapy", thus making this section inconsistent with the rest of the regulation. 1126.54(a)(17) should read "Any medical services, procedures, or pharmaceuticals related to infertility **therapy**, including surrogacy services."

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REQUEST FOR PROPOSAL

FOR A

MANDATORY MEDICAL ASSISTANCE MANAGED CARE PROGRAM FOR BUCKS, CHESTER, DELAWARE, MONTGOMERY, AND PHILADELPHIA COUNTIES

Issuing Office: Department of Public Welfare
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RFP DEFINITIONS (CONT.)

Health Maintenance Organization (HMO) — A public or private organization organized under State law that is a federally qualified HMO; or meets the State Plan's definition of an HMO. (A copy of the State Plan can be found in the HealthChoices Bidders' Library.)

HealthChoices — The name of Pennsylvania's 1915(b) waiver program to provide mandatory managed health care to MA recipients in Bucks, Chester, Delaware, Montgomery, and Philadelphia Counties.

HealthPASS — The name of Pennsylvania's current 1915(b) waiver program which provides mandatory managed health care to MA recipients residing in five (5) CAO districts of South and West Philadelphia County.

In-Plan Services — Services which are the responsibility of the HMO under the HealthChoices Program.

Inquiry — Any member's request for administrative service, or information, or to express an opinion. Whenever specific corrective action is requested by the member, or determined to be necessary by the HMO, it should be classified as a complaint.

Issuing Office — The Department's Division of Procurement.

Juvenile Detention Center — A publicly administered, secure residential placement for:

- Children alleged to have committed delinquent acts who are awaiting a court hearing;
- Children who have been adjudicated delinquent and are awaiting disposition or awaiting placement; and
- Children who have been returned from some other form of disposition and are awaiting a new disposition (i.e., court order regarding custody of child, placement of child, or services to be provided to the child upon discharge from the Juvenile Detention Center).

Maternity Care Payment — For each birth, or other second or third trimester pregnancy outcome, the Department will make a one-time Maternity Care Payment to the HMO who is responsible for the mother on the date of birth or other pregnancy outcome.

Medical Necessity — Determinations of medical necessity for covered care and services, whether made on a prior authorization, concurrent, or post-utilization basis, shall be in writing, be compensable under MA, and be based on the following standards. The plan shall base its determination on medical information provided by the individual's family and the primary care practitioner, as well as any other providers, programs, and agencies that have evaluated the individual. Medical necessity determinations must be made by qualified and trained providers. Satisfaction of any one of the following standards will result in authorization of the service:

- The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition, or disability.

RFP DEFINITIONS (CONT.)

- The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental, or developmental effects of an illness, condition, injury, or disability.

- The service or benefit will assist the individual to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the individual and those functional capacities that are appropriate for individuals of the same age.

Member or Enrollee — A person eligible to receive medical services under the MA Program in the Commonwealth of Pennsylvania and who is covered by the HealthChoices Program.

Michael Dallas Model Waiver (MDMW) — A program operating under a federal waiver that provides essential home care services, beyond the scope of traditional MA, to technology-dependent children under age twenty-one (21). The goal is to maintain the children in the community, thus avoiding an institutional setting.

Midwifery Practice — Management of the care of essentially normal women and their normal neonates (initial twenty-eight (28) day period). This includes intrapartum, postpartum, and gynecological care. The midwife is authorized and required to do the following:

- Prescribe medical, therapeutic, and diagnostic measures for essentially normal women and their normal neonates in accordance with the midwife protocol or a collaborative agreement or both.

- Administer specified drugs as provided for in collaborative agreements or as directed by a collaborating physician for a specific patient and, if specifically authorized to do so in a collaborative agreement, relay to other health care providers medical regimens prescribed by the collaborating physician, including drug regimens.

- Perform medical services in the care of women and newborns that may be beyond the scope of midwifery, if the authority to perform those services is delegated by the collaborating physician in the collaborative agreement, the delegation is consistent with standards of practice embraced by the midwife and the relevant physician communities in this Commonwealth.

Minority Business Enterprise — A business concern that is:

- A sole proprietorship, owned and controlled by a minority;

- A partnership or joint venture controlled by minorities in which fifty-one percent (51%) of the beneficial ownership interest is held by minorities; or

- A corporation or other entity controlled by minorities in which fifty-one percent (51%) of the voting interest and fifty-one percent (51%) of the beneficial ownership interest are held by minorities.

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