STATEMENTS OF POLICY

Title 28—HEALTH AND SAFETY

DEPARTMENT OF HEALTH

[28 PA. CODE CH. 9]

Approval of Provider Contracting Arrangements Between HMOs and PHOs, POs and IDSs

The Department of Health (Department) adopts the statement of policy at Chapter 9, Subchapter D (relating to PHOs, POs and IDSs—statement of policy) as set forth in Annex A.

The Department has the statutory obligation to review contracts between the health maintenance organizations (HMOs) and hospitals and practitioners which provide medical, dental and related services on behalf of the HMOs. See, section 8 of the Health Maintenance Organization Act (act) (40 P. S. § 1558(a)). Under the Department's former policy, HMOs generally were permitted to contract only directly with hospitals and practitioners on an individual basis. The purpose of this statement of policy is to permit HMOs to contract with various forms of integrated delivery systems (IDSs) including physician-hospital organizations (PHOs) and physician organizations (POs) rather than only directly with hospitals and other practitioners. This statement of policy outlines the relevant provisions which shall be included in contracts between HMOs and IDSs, and clarifies the standards to be used by the Department in reviewing and approving these contracts.

Background

The Department is aware that providers throughout this Commonwealth are organizing themselves into systems which seek to integrate the delivery and financing of health care on the local level, with the ultimate purpose of contracting with HMOs to provide health services to HMO members with various degrees of financial risk transfer and assumption. The Department understands that there are varying motivations for these developments, including, but not necessarily limited to: arguments that cost-effective patient care utilization and quality management can best be provided on the local level by local providers with local decision-making authority; provider interest in increasing their share of the surplus created by the application of sound cost-effective medical management to HMO patients; the potential of simplifying the complexities and administrative burdens involved in direct provider contracting with multiple HMOs and managed care organizations; and the potential of increased efficiency and cost-effectiveness through local provider control of multiple provider and health resources in integrated systems of care.

The generic name given to these efforts is IDSs. A great deal of the activity, however, is being undertaken by hospitals and members of their medical staffs and are called PHOs. Other efforts are being undertaken solely by physicians, and these organizations are known as POs or individual practice associations (IPAs). Some integrated delivery systems are for-profit, others are nonprofit. Most are developed, owned and controlled by providers. Others are for-profit, nonprovider-owned ventures. Some include community involvement and are known as physician-hospital community organizations. Most IDSs seek to contract with HMOs for the provision of a full range of covered services to HMO enrollees, including ambulatory visits to primary care physicians and specialists, in- and out-patient hospital services, diagnostic testing, and the like. Some IDSs, however, seek to contract for the provision of a restricted range of integrated benefits or services, such as a radiology IDS or cardiology IDS. One type of specialized IDS currently utilized in the HMO industry is the capitated behavioral health managed care organization. These organizations contract with HMOs to provide on a fixed price basis, usually capitation, the full range of required drug and alcohol abuse treatment and mental health treatment services offered in a typical HMO benefit package.

The challenge faced by the Department is to establish guidelines for HMO contracts with IDSs in their various manifestations and structures which provide for adequate oversight to protect consumers against undertreatment or poor quality care but which do not impose excessive or unreasonable regulatory requirements which would thwart their development in this Commonwealth. The Department also notes that recognition of IDSs has the potential of increasing competition and assisting marketplace forces in containing health care costs by making it easier for new HMO applicants to build adequate provider networks simply by contracting with one or more PHOs, POs or IDSs rather than individually with multiple providers.

During the development of IDS standards, the Department considered separate licensing of IDSs, perhaps as risk-assuming preferred provider organizations (PPOs) which are not licensed insurers. It has not adopted this position. In lieu of separate licensure, the Department will protect the public against the threat of undertreatment or poor quality care through the Department's statutory authority to review and approve HMO provider contracts with IDSs and other providers. See, section 8 of the act. The public also will be protected financially through a guideline establishing inclusion within provider contracts of a provision requiring IDSs and IDS participating providers to hold HMO members financially harmless and prohibiting IDS participating providers from billing HMO members for covered services, other than for authorized copayments, even in the event of the insolvency of the IDS, HMO or nonpayment by the IDS or HMO to the participating provider.

This oversight structure is predicated on the premise that most IDSs will be contractors to licensed HMOs. However, IDSs also seek to be contractors to health plans other than HMOs, including risk-assuming PPOs (both risk-assuming PPOs which are licensed insurers, and risk-assuming PPOs which are not licensed insurers, as defined in the joint Insurance and Health Department PPO regulations, 31 Pa. Code Chapter 152 (relating to preferred provider organizations)) and Blue Cross/Blue Shield plans. Likewise, there is interest in and uncertainty regarding the implications of an IDSs receiving a capitation directly from a self-funded employe health benefit plan, including the impact, if any, of the Federal Employee Retirement Income Security Act (ERISA). Because these issues extend beyond the Department's authority over HMO provider contracts which is the basis of this statement of policy, the Department intends to work with the Insurance Department to develop joint health plan-IDS contracting standards. It is the Department's

position that removal of regulatory uncertainty regarding IDS risk-assumption from health plans other than HMOs will advance competition.

The Department has been asked to consider the applicability of these IDS contracting standards to behavioral health providers. Those providers which accept risk in contracts with political subdivisions or other nonlicensed entities are required by statute to be licensed as HMOs or PPOs. Those contracts between behavioral health providers and licensed entities shall meet these IDS contracting standards.

The Department has been approached by potential sponsors of super-PHOs, whereby multiple PHOs came together to form an entity which would contract on behalf of its member PHOs with HMOs. The multiple-layered complex organizations, with responsibility flowing downward from HMOs through the super-PHO to multiple PHOs and ultimately to individual providers, have the potential of losing accountability and responsiveness to consumer needs. While desiring to offer flexibility and support innovation in health service delivery system design, the Department must ensure that specific accountability for quality of care oversight is well defined and that prompt corrective action authority exists on behalf of both the HMO and the Department if quality problems arise. It is essential that these issues are adequately addressed in all levels of provider contracting, and this statement of policy addresses the Department's expectations for all forms of HMO-IDS and IDS-participating provider contracting.

The Department intends to remove any barriers to HMO-IDS contracting by clarifying the applicable rules. Ultimately, however, the extent to which HMOs choose to contract with IDSs will depend upon economic and organizational factors beyond the Department's control.

Insofar as the Department's regulatory authority and interests extend, this statement of policy supersedes an interim policy set forth to the HMO industry in a memo dated January 10, 1995, entitled, "HMOs and Physician Hospital Organizations," signed by the then Insurance Commissioner and Secretary of Health. The Department will accept HMO filings for review and approval of proposed IDS provider contracts immediately upon publication of this statement of policy in the *Pennsylvania Bulletin*.

This statement of policy is issued in conjunction with a companion statement of policy issued by the Insurance Department. Contracts between HMOs and IDSs are subject to scrutiny by both the Department and the Insurance Department. Accordingly, both statements of policy must be consulted to gain a clear understanding of the entire contract review process that is applicable to contracts between HMOs and IDSs.

The Department has attempted to adopt user-friendly procedures for prompt review and approval of HMO-IDS provider contracts. HMO filers specifying their commitment to oversee IDS contractor quality of care and related functions in accordance with the delegation authority standards adopted by the Nationally recognized accreditation organization for managed care plans, the National Committee for Quality Assurance (NCQA), need not submit detailed documentation of oversight plans. However HMOs will be held accountable in the course of Department monitoring for adequate monitoring and oversight of their IDS subcontractors and for prompt identification and corrective action of any quality of care problems. In addition, the Department is adopting a 45-day deemer provision. If an HMO-IDS provider contract filing is not approved or disapproved within 45 days of date of receipt, it will be deemed approved.

Purpose

The purpose of this statement of policy is to provide guidance to HMOs and IDSs, including PHOs and POs, on the standards the Department will utilize in reviewing and approving proposed provider contracts between HMOs and these entities for the provision of covered services to HMO members.

This statement of policy will expedite the ability of HMOs to contract with IDSs systems. It offers the many provider groups within the Commonwealth, particularly hospital-medical staff-sponsored PHOs and physician-sponsored physician organizations, a method of achieving their goals.

Finally, the statement of policy will promote competition and cost containment by making it easier for new HMO applicants to build acceptable delivery systems needed to satisfy licensing requirements.

Form and Effect

This statement of policy provides guidance regarding the standards to be utilized by the Department in the review and approval of proposed providers contracts between HMOs, IDSs and IDS participating providers for the provision of health care services to HMO members. This statement of policy does not constitute a rule or regulation entitled to the force and effect of law.

Fiscal Impact and Paperwork Requirements

Adoption of this statement of policy removes ambiguity regarding the standards to be applied to contractual relationships between HMOs and IDSs. It further provides a mechanism by which significant developmental and legal funds and resources already expended in this Commonwealth by hospitals and physicians to develop IDSs can be recognized through submission of contract proposals between HMOs and these systems for review and approval by the Department.

Any increased cost in implementing this statement of policy should be outweighed by the overall cost savings that should be realized by consumers in their health care costs. HMOs and IDSs will require less time to research the Department's standards prior to developing and submitting specific proposed contracts for review and approval. Since this statement of policy, unlike earlier preliminary proposals calling for licensure of certain full-risk assuming IDSs, does not require a separate license of an IDS assuming financial risk from an HMO, significant funds will not need to be expended in preparation of licensure applications.

Further Information

Persons desiring more information regarding this statement of policy should contact Frank Clark, Acting Director, Bureau of Health Care Financing, P. O. Box 90, Room 1030, Harrisburg, PA 17108, (717) 787-5193 or Thomas J. Chepel, C.L.U., C.P.C.U., Director of the Bureau's Division of Health Care Plans.

Effective Date

This statement of policy is effective immediately upon publication in the *Pennsylvania Bulletin*.

DANIEL F. HOFFMAN,
Acting Secretary

(*Editor's Note*: For a related statement of policy of the Insurance Department, see 26 Pa.B. 1636 (April 6, 1996).)

(*Editor's Note*: The regulations of the Department of Health, 28 Pa. Code Chapter 9, are amended by adding a statement of policy at §§ 9.401—9.416 to read as set forth in Annex A.)

Fiscal Note: 10-141. (1) General Fund; (2) Implementing Year 1996-97 is $ minimal; (3) 1st Succeeding Year 1997-98 is $ minimal; 2nd Succeeding Year 1998-99 is $ minimal; 3rd Succeeding Year 1999-00 is $ minimal; 4th Succeeding Year 2000-01 is $ minimal; 5th Succeeding Year 2001-02 is $ minimal; (4) Fiscal Year 1995-96 $12,415,000; Fiscal Year 1994-95 $12,313,000; Fiscal Year 1993-94 $11,048,000; (7) General Government Operations; (8) recommends adoption. The increased costs to review additional HMO-IDS provider contracts is expected to be minor and can be achieved with existing staff resources.

Annex A

TITLE 28. HEALTH AND SAFETY

PART I. GENERAL HEALTH

CHAPTER 9. MANAGED CARE ORGANIZATIONS

Subchapter D. PHOs, POs AND IDSs—STATEMENT OF POLICY

Sec.

§ 9.401. Applicability and purpose.

(a) This subchapter provides information to HMOs, providers, POs and IDSs concerning how the Department proposes to exercise its authority under the HMO Act and related acts to review, approve and monitor the establishment of provider contracts between HMOs and IDSs. The information will enable delivery systems and HMOs to negotiate to establish provider contracts in a manner likely to be found acceptable by the Department. This subchapter expresses the present intentions of the Department with respect to review and approval of provider contracts between and among HMOs, IDSs and providers participating in the systems.

(b) This subchapter should be reviewed by persons who undertake to establish, operate and maintain an IDS whose primary purpose is to contract with one or more HMOs for the provision of health care services to HMO members. These persons should also consult the Insurance Department's statement of policy on this subject at 31 Pa. Code Chapter 301, Subchapter I (relating to contractual arrangements between HMOs and IDSs—statement of policy).

§ 9.402. Definitions.

The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise:

Contract—An arrangement between an HMO and a provider, organization or group of providers under which the providers:

(i) Agree to provide or arrange to provide a defined set of health care services to HMO members.

(ii) May agree to assume responsibility for conduct of the quality assurance, utilization review, credentialling, provider relations or claims management or related functions.

(iii) Is reimbursed either directly on a fee-for-service basis or through a financial risk arrangement.

Department—The Department of Health of the Commonwealth.

HMO—Health Maintenance Organization—An organized system which combines the delivery and financing of health care and which provides basic health services to voluntarily enrolled members for a fixed prepaid fee.

HMO Act—The Health Maintenance Organization Act (40 P. S. §§ 1551—1567).

IDS—Integrated Delivery System—A partnership, association, corporation or other legal entity which enters into contractual arrangements with an HMO; employs or has contracts with providers (participating providers) and agrees under its arrangements with an HMO, to provide or arrange for the provision of a defined set of health care services to HMO members covered under an HMO benefits contract principally through its participating providers, assumes under the arrangements some responsibility for conduct, in conjunction with the HMO and under compliance monitoring of the HMO, of quality assurance, utilization review, credentialling, provider relations or related functions, may perform claims processing and other functions, and which assumes to some extent, through capitation reimbursement or other risk-sharing arrangements, the financial risk for provision of the services to HMO members.

LS-IDS—Limited service integrated delivery system—An IDS which contracts with an HMO for a limited or restricted range of health care services, including pharmacy, dental, cardiology, radiology or behavioral health, even though the limited or restricted services may include inpatient, outpatient, diagnostic testing, treatment and facility charge coverage for limited services being provided.

PHO—Physician-hospital organization—An IDS jointly owned and controlled by a hospital and a physician.

PO—Physician organization—An IDS primarily owned and controlled by physicians, including a model whereby physicians are the primary shareholders of the IDS. A PO may assume financial risk and contractual responsibility from an HMO to provide hospital and other nonphysician services by contracting with hospitals and other providers which may not be members of the PO, or it may assume financial risk only for the professional component of an HMO benefit package and share in surplus or deficits relating to targeted hospitals and other health services utilization. POs also may contract with other physician POs or multispecialty practices and need not have provider contracts with nonphysician providers in order to share risk with an HMO by assuming liability for part or all of a budget shortfall.

Physician-hospital-community organization—An IDS typically not-for-profit, governed by a board that includes physicians, hospital representatives and community members, including, consumers, business representatives and government representatives that may engage in community health assessment or other community benefit activities beyond contracting to provide health services.

Provider—Any "health care facility" or "health care provider" as those terms are defined under section 802(a) of the Health Care Facilities Act (35 P. S. § 448.802); a mental health facility licensed by the Department of Public Welfare; or an individual licensed by the Commonwealth to practice any profession involved in the healing arts. The term includes hospitals, mental health treatment facilities, drug and alcohol treatment facilities, physicians, dentists, podiatrists, psychologists, nurses, physician assistants, certified registered nurse practitioners, physical therapists, chiropractors, optometrists and pharmacists.

S-PHO—Super physician-hospital organization—A partnership, association, corporation or other legal entity created by two or more PHOs for the purpose of entering into provider contracts with HMOs collectively on behalf of the participating PHOs and of the providers participating in each of the participating PHOs.

S-PO—Super-physician organization—A partnership, association, corporation or other legal entity created by two or more POs for the purpose of entering into provider contracts with HMOs collectively on behalf of the participating POs and of the providers participating in each of the participating POs.

§ 9.403. Licensure requirements.

An HMO may contract with one or more IDSs under contractual arrangements which have been reviewed and approved by the Department and which meet the following standards:

(1) The HMO may contract with an IDS for the provision of care by IDS participating providers to HMO members. Any contract between an HMO and an IDS shall be incorporated by reference in all contracts between the IDS and providers with which the IDS contracts to provide services to HMO members, and shall be provided by the IDS to each of its participating providers upon request. Both the contract between the HMO and the IDS and the contract between the IDS and participating providers, shall include consumer hold-harmless language acceptable to the Department.

(2) An HMO may contract with an IDS for the performance of quality assurance, utilization review and credentialling of those providers who will provide services to the HMO's members, so long as the utilization management, quality assurance and credentialling standards are submitted by the HMO and approved in advance by the Department and the implementation is subject to periodic review and compliance verification by the HMO, the Department and other external agencies. The standards shall be considered those of the HMO.

(3) An HMO may delegate primary care "gatekeeping" functions to an IDS, and an IDS may delegate the functions to its providers. The IDS may utilize primary care physician "gatekeepers" if the HMO has an acceptable plan of quality of care oversight to ensure that the IDS and its participating providers do not provide inadequate or poor quality care arising out of its reimbursement incentives.

(4) An HMO and IDS may utilize capitation and other financial reimbursement arrangements agreed to in the contracts between the HMO and IDS and between the IDS and its participating providers, as incentives for appropriate and cost-effective utilization of services.

(5) The IDS may arrange for its providers to assume financial risk from an HMO in the form of a fixed capitation fee, which does not vary by actual utilization of services, or percentage of premium arrangement without first receiving a separate license as an insurance company, risk-assuming PPO which is not a licensed insurer, HMO or otherwise. An IDS, likewise, may arrange for its providers to participate only in bonus payment systems based on favorable utilization or to limit provider risk to an amount withheld from provider reimbursement and distributed back to providers only if utilization or budget targets are met.

§ 9.404. Financial protection of HMO members served through IDSs.

To maximize protection of those HMO members who may be served through IDS and IDS participating providers from the adverse impact of an IDS's inability to pay its participating providers or the providers balance billing members for HMO covered services, the Department will not approve a provider contract between an HMO and IDS unless:

(1) The HMO-IDS contract and IDS participating provider contracts contain member financial hold harmless provisions acceptable to the Department which would prevent the IDS and IDS participating providers from billing HMO members for covered services (other than for authorized copayments, coinsurance or deductibles) under any circumstances, including the insolvency of the HMO or the IDS. (See § 9.407(a)(1) (relating to minimum compliance provisions which should be contained in an IDS-participating provider or compliance amendment) as well as the Insurance Department's statement of policy regarding HMO-IDS contracts at 31 Pa. Code § 301.311(c) (relating to annual and quarterly filings)).

(2) Provision of HMO covered services to HMO members are not delayed, reduced, denied or otherwise hindered because of the financial or contractual relationship between the HMO and IDS, and the HMO-IDS contract protects the HMO's members from being billed by providers, whether or not participating, by the IDS.

(3) The HMO-IDS contract contains a provision requiring the IDS and its participating providers to comply with data reporting requirements, including encounter, utilization and reimbursement methodology required by the Department. The Department's purpose in reviewing provider reimbursement methodology is to identify reimbursement methods which may lead to inadequate or poor quality care and to ensure that the HMO and IDS have adequate systems to monitor quality of care and prevent undertreatment and that reimbursement methodologies are not so inadequate so as to result in undertreatment or poor quality care. The Department reserves the right to require submission of actual rates of payment in those instances in which the information is necessary in its judgment, to diagnose and correct quality of care problems relating to reimbursement incentives or inadequate reimbursement levels or to investigate consumer or provider grievances alleging quality of care deficiencies arising out of reimbursement methods or levels of payment.

§ 9.405. Review and approval of HMO-IDS provider contracts.

For an HMO-IDS provider contract to be found acceptable and approved by the Department and not required to be renegotiated under section 8(a) of the HMO Act (40

P. S. § 1558(a)) the contract shall contain the following or substantially similar provisions:

(1) The IDS acknowledges and agrees that only those IDS participating providers who meet the HMO's credentialling and provider contracting standards may participate in the HMO and provide services to HMO members, and that the ultimate authority to accept IDS providers for participation or to terminate participation is retained by the HMO.

(2) The IDS acknowledges and agrees that the HMO is required to establish, operate and maintain a health service delivery system, quality assurance system, provider credentialling system, member grievance system and other systems meeting Department standards, and is directly accountable to the Department for compliance with the standards and for the provision of high-quality, cost-effective care to HMO members. Nothing in the HMO-IDS agreement be construed to in any way limit the HMO's authority or responsibility to meet standards or to take prompt corrective action to address a quality of care problem, resolve a member grievance or to comply with a regulatory requirement of the Department.

(3) The IDS agrees to provide the HMO and Department with access to medical and other records concerning the provision of services to HMO members by and through the IDS and its participating providers.

(4) The IDS agrees to collect and provide the HMO with utilization, financial and other data for the purposes of comparative performance analysis of HMO and IDS effectiveness.

(5) The IDS agrees that any delegation of authority or responsibility for provider credentialling and relations, quality assessment, utilization review and other functions by the HMO to IDS shall be subject to performance monitoring by the HMO and Department and is subject to independent validation by the HMO, the Department or an independent quality review/assessment organization approved by the Department.

§ 9.406. Review and approval of IDS-participating provider contracts.

(a) *Review of contract by Department.* In addition to the HMO-IDS contract, the provider contracts between the IDS and its participating providers which enable the IDS to provide care to HMO members shall be submitted for review and approval of the Department.

(b) *Methods of contracting.*

(1) Several methods of IDS-participating provider contracting are acceptable to the Department as follows:

(i) Each IDS-participating provider may enter into the HMO's standard provider agreement approved by the Department, which shall include an amendment or rider which reflects any special terms or conditions relating to the HMO-IDS agreement. The standard provider agreement with the amendment or rider should be signed by the HMO, the participating provider and the IDS. The amendment or rider should be filed by the HMO for review and approval of the Department.

(ii) The IDS may utilize a contract between itself and its participating providers, if the IDS-participating provider contract incorporates by reference the agreements between the IDS and each HMO with which it contracts, which HMO-IDS agreements shall be provided, upon request, prior to the effective date, to each IDS participating provider. The financial amounts in the HMO-IDS agreements may be redacted from the copies of the agreements the IDS shall provide to its participating providers. Unique terms or conditions relating to each HMO-IDS arrangement may be reflected in an amendment or rider to the IDS-participating provider contract. The IDS-participating provider contract, any amendment to the contract and a list of providers who have entered into the contract shall be filed by the HMO for review and approval of the Department.

(2) Whichever compliance method is utilized, the compliance provisions specified in § 9.407 (relating to minimum compliance provisions which should be contained in an IDS-participating provider or compliance amendment) should be included.

(c) *Signatures required.* The HMO-IDS-participating provider contract or compliance amendment shall contain three signatures representing the HMO, IDS and participating provider. If the standard IDS-participating provider contract grants signature authority to the IDS to enter into provider contracts on behalf of participating providers, it will not be necessary for each participating provider to sign the amendment or rider.

§ 9.407. Minimum compliance provisions which should be contained in an IDS-participating provider or compliance amendment.

For the Department to accept and approve a participating provider contract between an IDS and a participating provider applicable to provision of services to HMO members and not require renegotiation of the contract under section 8(a) of the HMO Act (40 P. S. § 1558(a)), each IDS-participating provider contract or compliance amendment shall contain provisions substantially similar to the following:

(1) Provider agrees that in no event, including, but not limited to, nonpayment by the HMO or IDS, the insolvency of HMO or IDS, or breach of this agreement, shall provider bill, charge, collect a deposit from, seek compensation, remuneration or reimbursement from, or have any recourse against member/enrollee or persons other than HMO or IDS acting on their behalf for services listed in this agreement. This provision shall not prohibit collection of supplemental charges or copayments on HMO's behalf made in accordance with terms of the contract between HMO and member/enrollee.

> Provider further agrees that (1) the hold harmless provision shall survive the termination of the (applicable provider contract) regardless of the cause giving rise to termination and shall be construed to be for the benefit of the HMO member/enrollee and that (2) this hold harmless provision supersedes any oral or written contrary agreement now existing or hereafter entered into between provider and member/enrollee or persons acting on their behalf.
>
> No modification, addition or deletion to the provisions of this section shall become effective without the specific prior written approval of the Department of Health.

(2) Provider acknowledges and agrees that nothing in the agreement shall be construed to limit: (a) the authority of the HMO to ensure provider participation in and compliance with HMO's quality assurance, utilization management, member grievance and other systems and procedures; (b) the Department of Health's authority to monitor the effectiveness of HMO's systems and procedures or the extent to which the HMO adequately monitors any function delegated to IDS, or to require the HMO to take prompt corrective action regarding quality of care or consumer grievances and complaints; (c) HMO's

authority to sanction or terminate a provider found to be providing inadequate or poor quality care or failing to comply with HMO systems, standards or procedures as agreed to by the IDS. Provider agrees to participate in and abide by the decisions of the HMO's quality assurance, utilization management and member grievance systems.

(3) Provider agrees to cooperate with and provide HMO, the Department of Health, and any external quality review organization approved by the Department of Health, with access to member medical records for the purposes of quality assessment and quality improvement or investigation of member complaints or grievances. Provider further agrees to provide such information, including but not limited to encounter, utilization, referral and other data, that the IDS may require to be submitted to it for compliance with its own data reporting requirements or as required by the Department of Health.

(4) Provider acknowledges and agrees that in order to participate in the HMO he, she or it must meet the minimum credentialling standards established by the HMO as approved by the Department of Health and that the HMO retains sole authority to accept, reject or terminate an IDS provider who fails to meet such standards on a continuing basis.

(5) Provider acknowledges and agrees that any delegation by HMO to IDS under the HMO-IDS contract for performance of quality assurance, utilization management, credentialling, provider relations and other medical management systems, shall be subject to the HMO's oversight and monitoring of IDS performance. Provider further acknowledges and agrees that HMO, upon failure of IDS to properly implement and administer such systems or to take prompt corrective action after identifying quality, member satisfaction or other problems, may terminate its contract with IDS and that, as a result of such termination, provider's participation in the HMO may also be terminated.

(6) Provider acknowledges and agrees that, if in the judgment of HMO, the IDS provider has failed to cooperate with HMO in the provision of cost-effective, quality services to HMO members, or has failed to cooperate with and abide by the provisions of the HMO's quality assurance, utilization management or member grievance systems, or is found to be harming HMO patients, the HMO may terminate provider's participation in HMO.

§ 9.408. Delegation of medical management authority by an HMO to an IDS.

(a) For the Department to approve a provider contract between an HMO and an IDS, under which the HMO will delegate responsibility to the IDS for performance of provider credentialling, quality assurance, utilization management or other essential HMO functions, the HMO should submit with the request for review and approval, an IDS "monitoring plan," which should include, at the minimum, each of the following:

(1) A clear definition of the quality assurance, utilization management and credentialling standards to be utilized and applied by the IDS to HMO members.

(2) A description of how the HMO will monitor the effectiveness of any quality assurance activities delegated to the IDS, including at least the following:

(i) Periodic reporting by the IDS quality assurance committee to the HMO.

(ii) Review and approval by the HMO of the IDS quality assurance committee's annual work plans and objectives.

(iii) Integration into the ISD's quality assurance system of the standards approved by the Department and the Department's periodically required external quality reviews by approved external quality review organizations.

(iv) A plan for random sample re-review and validation of the results of quality assurance studies, credentialling, utilization management decisions, and similar activities undertaken by the IDS on behalf of the HMO.

(v) HMO input into design of methodology of focused medical record reviews undertaken by the IDS to measure and improve quality of care being provided to HMO members by IDS participating providers.

(vi) A description of the relationship between respective authorities of the HMO's medical director and quality assurance/utilization review staff and the IDS's medical director and quality assurance/utilization review staff.

(b) Alternatively, in recognition of the managed care industry's wide acceptance of the National standards developed by the National Committee for Quality Assurance (NCQA) in conjunction with its voluntary accreditation program, in lieu of submission of the monitoring plan specified in subsection (a), the filing HMO need only certify in its submission letter its convenant to comply with NCQA managed care organization contractor delegation standards.

(c) The effectiveness of an HMO's monitoring of the quality of care and other performance of an IDS, including, if applicable, compliance with NCQA contractor delegation standards, and of the IDS's actual provision of quality health care to HMO members shall be periodically reviewed by the Department through required submission and review of written reports, IDS quality assurance work plans submitted to the HMO, onsite visits to and inspections of the HMO and IDS, periodic external quality assessment of the HMO, and, if applicable, periodic external quality assessment of the IDS.

(d) If the Department determines, through periodic review, external quality assessment by an approved external quality review organization, or otherwise that an HMO is deficient in its monitoring of delegated responsibilities to an IDS, the Department may require the HMO to file, receive approval of and implement an appropriate "corrective action plan."

§ 9.409. Delegation of member grievance system responsibility to an IDS.

(a) An HMO may not delegate responsibility for HMO member grievance system operation or resolution to an IDS contractor. The HMO shall apply its Department-approved grievance system uniformly to all members, including those members being served through an IDS contractor.

(b) One or more representatives of the IDS, with no prior involvement in the grievance under consideration, may serve as members of the first or second level grievance review committees established by the HMO to hear the grievances of members served by the IDS. (See § 9.73 (relating to subscriber grievance system).)

§ 9.410. Contents of an HMO filing for review and approval of an IDS provider contract.

(a) An HMO requesting approval of a standard generic form IDS contract to be utilized in contracting with one or more IDSs shall submit a filing to the Department requesting approval and containing the following elements:

(1) A cover letter including:

(i) Indication, by page and section number reference, where in the HMO-IDS generic contract and in the IDS-participating provider contract, the requested compliance provisions of §§ 9.405 and 9.407 (relating to review and approval of HMO-IDS provider contracts; and minimum compliance provisions which should be contained in an IDS-participating provider or compliance amendment) are found.

(ii) A certification that the HMO will monitor delegation of medical management responsibilities to the IDS by complying with National Committee for Quality Assurance (NCQA) delegation standards or has included a "monitoring plan" as described in § 9.408 (relating to delegation of medical management authority by an HMO to an IDS).

(iii) A brief description of the reimbursement methodologies to be utilized by the HMO in reimbursing the IDS, and the reimbursement methodologies to be utilized by the IDS, in turn, to reimburse its participating provider.

(2) A copy of the proposed standard generic provider contract between the HMO and IDS, containing the provisions requested in § 9.405.

(3) A copy of the standard generic form of all provider contracts, including, compliance amendments/riders between the IDS and its participating providers, containing the provisions requested in § 9.407.

(4) A copy of the HMO's medical management delegation monitoring plan, in accordance with § 9.408, if the HMO is unwilling or unable to commit to utilization of NCQA delegation standards.

(b) In those cases in which the HMO is contracting with an IDS utilizing its own participating provider contracts rather than generic IDS-participating provider contracts developed by the HMO, the HMO shall include copies of the specified IDS's generic provider contracts in the filing, identify by name, address and telephone number the IDS, and include a list of the IDS's participating providers.

(c) In those cases in which the HMO is utilizing individually negotiated and unique HMO-IDS contracts rather than a generic form contract, these IDS-specific contracts shall be submitted and the cover letter shall identify by name, address and telephone number the IDS and include a list of the IDS's participating providers. If so filled, these case-specific HMO-IDS contracts may delete confidential payment rates otherwise included therein.

(d) In those cases in which the HMO enters into a standard form generic HMO-IDS contract, utilizing a previously filed and approved contract form, the HMO need only file with the Department a brief "Notice and Certification" notifying the Department that the HMO has entered into a contract with a particular IDS, identifying the IDS by name, address, telephone number and contact person, including a list of IDS participating providers, and certifying that it has used whatever generic contract that has been previously approved. If the HMO-IDS contract is generic, but the HMO-IDS participating provider contracts are not, the "Notice and Certification" letter also should include generic copies of the IDS-participating provider contracts and an identification, by page and section number, of the compliance provisions specified in § 9.407.

(e) A filing will be deemed "approved" by the Department if it is not specifically disapproved within 45 days of its receipt by the Department.

§ 9.411. Special products filings.

(a) If the HMO intends to market a special product at a special premium to HMO members willing to limit their utilization to a particular IDS's participating provider network, the HMO shall make an appropriate filing for prior review and approval of the Department. The filing shall address the capacity of the IDS participating provider network to provide adequate, accessible and available health care to members enrolling in the special product.

(b) If, as a result of an IDS contract, the HMO intends to expand its service area, it shall submit an appropriate service area expansion request.

§ 9.412. Super-PHOs.

(a) An HMO seeking review and approval of provider contracts with a super-PHO shall submit each layer of provider contracts between each level of subcontracting providers and HMO and ensure that all provider contracts meet the standards in this subchapter.

(b) HMOs seeking review and approval of provider contracts with super-PHOs should carefully explain in their application any intended delegation of quality assurance, utilization management, provider credentialling and related functions through the various layers of the super-PHO.

§ 9.413. Provider-patient complaint systems.

HMOs are encouraged to create a fundamentally fair provider grievance system, whereby a provider dissatisfied with a precertification or utilization management decision of an HMO, or who desires to advocate for approval of a particular treatment, treatment plan or referral on behalf of a patient may do so without fear of reprisal from the HMO.

§ 9.414. External quality review of an IDS.

An IDS which voluntarily undergoes an external quality review by an external quality review organization approved by the Department, may receive consideration of the review in fulfilling its quality assurance oversight obligations and the obligations of one or more HMOs with which it may contract, if the following apply:

(1) The arrangement is approved prior to implementation by one or more of its contracting HMOs and the Department.

(2) The results of the external quality review are shared with the HMO and the Department.

(3) Actual conduct of the external review, including scheduling thereof, is coordinated with the Department.

(4) Department staff have the opportunity to participate in the external quality review of the IDS.

§ 9.415. HMO-IDS filing requirement.

HMO-IDS contracts in force on April 6, 1996, should be filed with the Department, but all reimbursement levels or rates of payment may be deleted as being confidential.

§ 9.416. IDS contracts with political subdivisions.

IDS contracts with political subdivisions shall contain the provisions outlined in this subchapter unless the IDS is licensed as an HMO or risk-assuming preferred provider organization.

[Pa.B. Doc. No. 96-576. Filed for public inspection April 5, 1996, 9:00 a.m.]

Title 31—INSURANCE

INSURANCE DEPARTMENT

[31 PA. CODE CH. 301]

Contractual Arrangements between HMOs and IDSs

This statement of policy is adopted under the authority of the Health Maintenance Organization Act (HMO Act) (40 P. S. §§ 1551—1568). Specifically, the Insurance Commissioner's authority with respect to contracts entered into by Health Maintenance Organizations (HMOs) is set forth at section 8(b) of the HMO Act (40 P. S. § 1558(b)).

Introduction

The Insurance Department (Department) hereby adopts amendments to Chapter 301 (relating to health maintenance organizations) that appear in Annex A, regarding the contractual arrangements between HMOs and entities generally referred to as Integrated Delivery Systems (IDSs). This statement of policy sets forth guidelines regarding, and the procedures for reporting, contractual arrangements between HMOs and risk-bearing IDSs and suggests safeguards to be adhered to by HMOs to protect their members against the threat posed by financially troubled or insolvent IDSs. It also clarifies when an IDS is not required to be licensed as an HMO.

Applicability

This statement of policy applies to HMOs that elect to contract with risk-bearing IDSs. Accordingly, when an HMO contracts with an IDS, so that the IDS will assume risk and perform other functions as indicated in section 8(b) of the HMO Act, in addition to the delivery of health care services, the HMO will file its IDS contracts with the Department. For purposes of this statement of policy, IDSs include physician-hospital organizations, physician organizations, physician-hospital-community organizations and super physician-hospital organizations.

This statement of policy supersedes the industry notice jointly issued by the Department and the Department of Health on January 10, 1995.

Background

Various entities throughout this Commonwealth are at present organizing themselves into systems which integrate the financing and delivery of health care. The ultimate purpose of these entities, referred to as IDSs, is to contract with HMOs to perform a variety of functions on behalf of HMOs, when varying degrees of financial risk are assumed by the IDSs. With the passage of time, as these entities develop in sophistication and complexity, increased risk may be assumed by the IDSs in order to acquire an additional portion of potential profits.

The Department is charged with protecting HMO members and the general public against the potential threat posed by financially troubled or insolvent HMOs. The Department's regulation of HMOs involves the oversight of various aspects of HMO business including HMO contractual relationships with IDSs. The Department believes that the public interest will be served by providing guidance to HMOs with respect to their risk-sharing practices with IDSs.

Purpose and Effect

The guidelines in this statement of policy are designed to assist HMOs in implementing prudent business practices and in identifying and addressing issues which might lead to an IDS insolvency which could negatively impact the financial integrity of the HMO.

This statement of policy outlines the guidelines the Department intends to use to determine whether an HMO's delegation of responsibilities to an IDS may have the potential to result in harm to the financial condition of the HMO. Further, the statement of policy establishes safeguards for the financial protection of HMO members served through IDS contracts, and sets forth preferred reporting procedures for HMOs that contract with one or more risk-bearing IDSs.

This statement of policy provides guidance only, and does not constitute a rule or regulation entitled to the force and effect of law.

Companion Statement of Policy

This statement of policy is issued in conjunction with a companion statement of policy issued by the Department of Health. HMOs are subject to regulation by both the Department of Health and the Department. Accordingly, both statements of policy must be consulted to gain a clear understanding of the processes that are applicable to contracts between HMOs and IDSs.

Fiscal Impact and Paperwork Requirements

Adoption of this statement of policy may result in additional cost and paperwork to the Commonwealth, HMOs and IDSs. Additional costs and paperwork should be outweighed by overall cost savings to consumers in the form of lower health care costs resulting from: (1) separate licensure not being required for the vast majority of IDSs; and (2) lower legal and consulting costs for HMOs and IDSs through the clear articulation of guidelines and procedures.

Contact Person

Questions relating to this statement of policy may be directed to Kenneth B. Allen, Director, Bureau of Licensing and Financial Analysis, Insurance Department, 1345 Strawberry Square, Harrisburg, PA 17120, (717) 787-2735.

Effective Date/Sunshine Date

This statement of policy is effective immediately upon publication in the *Pennsylvania Bulletin*. No sunset date has been assigned. However, the Department intends to review this statement of policy in 180 days to ascertain whether adjustments in this statement of policy are appropriate. (*Editor's Note*: The regulations of the Insurance Department are amended by adding a statement of policy at 31 Pa. Code §§ 301.101—301.303, 301.311—301.314 and 301.321 to read as set forth in Annex A.)

LINDA S. KAISER,
Insurance Commissioner

(*Editor's Note*: For a related statement of policy, see 26 Pa.B. 1629 (April 6, 1996).)

Fiscal Note: 11-139. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 31. INSURANCE

PART X. HEALTH MAINTENANCE ORGANIZATIONS

CHAPTER 301. HEALTH MAINTENANCE ORGANIZATIONS

Subchapter I. CONTRACTUAL ARRANGEMENTS BETWEEEN HMOs AND IDSs—STATEMENT OF POLICY

GENERAL PROVISIONS

CONTRACT FILINGS AND OTHER REPORTING

DEPARTMENT EXAMINATIONS

GENERAL PROVISIONS

§ 301.301. Definitions.

The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise:

Contract—An arrangement between an HMO and a risk-bearing IDS, whereby the IDS is obligated to perform marketing, enrollment, administrative or similar functions. Administrative functions do not include quality assurance, utilization review, credentialing, provider relations or related functions.

Examination Law—Sections 901—1013 of The Insurance Company Law of 1921 (40 P. S. §§ 323.1—324.13).

HMO—Health Maintenance Organization—An organized system which combines the delivery and financing of health care and the provision of basic health services to voluntarily enrolled members for a fixed prepaid fee, and is required to obtain a certificate of authority in accordance with applicable statutes and regulations (See sections 4 and 5.1 of the act (40 P. S. §§ 1554 and 1555.1) and §§ 301.41 and 301.42 (relating to prohibition against uncertified HMOs, and content of application for certificate of authority).

IDS—Integrated Delivery System—A partnership, association, corporation or other legal entity which enters into a contractual arrangement with an HMO; employs or has contracts with providers (participating providers); and agrees under its arrangements with an HMO, to provide or arrange for the provision of a defined set of health care services to HMO members covered under an HMO benefits contract principally through its participating providers, assumes under the arrangements some responsibility for conduct, in conjunction with the HMO and under compliance monitoring of the HMO, of quality assurance, utilization review, credentialing, provider relations, or related functions, may perform claims processing and other functions and which assumes to some extent, through capitation reimbursement or other risk-sharing arrangements, the financial risk for provision of these services to HMO members.

Provider—A "health care facility" or "health care provider" as those terms are defined under section 802(a) of the Health Care Facilities Act (35 P. S. § 448.802(a)), a mental health facility licensed by the Department of Public Welfare, or an individual licensed by the Commonwealth to practice a profession involved in the healing arts. The term includes hospitals, mental health treatment facilities, drug and alcohol treatment facilities, physicians, dentists, podiatrists, psychologists, nurses, physician assistants, certified registered nurse practitioners, physical therapists, chiropractors, optometrists and pharmacists.

Risk—The possibility of financial loss associated with contracts to perform a defined set of health care services for a predetermined portion of premium dollars.

§ 301.302. Applicability and purpose.

(a) This subchapter applies to HMOs which enter into contracts with risk-bearing IDSs.

(b) This subchapter provides guidance to HMOs desiring to enter into contracts with risk-bearing IDSs for the performance of a defined set of health care services. This subchapter suggests safeguards to be adhered to by HMOs to protect HMO members against the threat posed by financially troubled or insolvent IDSs.

(c) This subchapter is not applicable to HMOs that enter into agreements with persons or entities other than IDSs for the performance of claims processing, administrative services, marketing, enrollment and other related functions.

§ 301.303. Certificate of authority.

(a) HMOs are required to obtain a certificate of authority issued jointly by the Department and the Department of Health in accordance with applicable statutes and regulations. See sections 4 and 5.1 of the act (40 P. S. §§ 1554 and 1555.1) and §§ 301.41 and 301.42 (relating to prohibition against uncertified HMOs; and content of application for certificate of authority).

(b) Under the act, persons or entities are acting as an HMO and are obligated to obtain a certificate of authority if the person or entity directly or through arrangements with others does the following:

(1) Solicits or enrolls members in a plan that will deliver prepaid basic health services.

(2) Delivers prepaid basic health services to those members.

(c) If a person or entity is delivering prepaid basic health services to HMO members, but not soliciting or enrolling members in a plan, that person or entity is not required to obtain a certificate of authority. If the person or entity is delivering prepaid basic health services and performing administrative services or other similar functions, but not soliciting or enrolling HMO members, that person or entity is not required to obtain a certificate of authority.

CONTRACT FILINGS AND OTHER REPORTING

§ 301.311. Annual and quarterly filings.

(a) HMOs are obligated to file annual financial statements with the Commissioner, and other reports upon the Department's request, under section 11 of the act (40 P. S. § 1561).

(b) It has been the Department's practice to require the filing of quarterly financial statements by HMOs, under the authority contained in section 11 of the act.

(c) Under this authority, the Commissioner will require that HMOs which enter into contracts with IDSs, file a written report at the same time as the filing of the

HMO's annual financial statement in a form which will be available from the Department.

§ 301.312. Initial contract filing.

(a) An HMO shall file with the Department any contract entered into with an IDS under which the IDS will assume risk and perform other functions as indicated in section 8(b) of the act (40 P. S. § 1558(b)).

(b) Under this authority, the Commissioner will require that when an HMO initially enters into a contract with an IDS, the HMO shall file the contract with the Department not later than the filing of the next quarterly or annual financial statement, whichever occurs first, following the effective date of the contract, together with a written report in a form which will be available from the Department.

(c) If no quarterly financial statement is required by the Department, the Department requests that contracts with an IDS, together with a written report, be filed within 45 days of the effective date of the contract.

(d) Initial contract filings may be submitted with any additional information that may be appropriate for the Department's review, such as a cover letter describing the following:

(1) The extent to which functions are transferred to the IDS and the extent and type of services which will be provided by the IDS.

(2) The relationship between the IDS and the participating providers, and the manner in which services will be delivered by participating providers.

(3) The identities of IDS subcontractors.

(4) The reimbursement methodology, and a copy of security arrangements relating thereto, between the HMO and IDS.

§ 301.313. Filings upon contract changes.

(a) If a contract filed under § 301.312(a) (relating to initial contract filing) is amended, the HMO shall file the amended contract with the Department not later than the filing of the next quarterly or annual financial statement, whichever occurs first, following the effective date of the amendment.

(b) Upon filing with the Department of an applicable amended HMO contract with an IDS, the Department requests that the HMO submit a written report in a form which will be available from the Department.

(c) If no quarterly financial statement is required by the Department, the Department requests that the applicable amended contract, together with the written report, be filed within 45 days of the effective date of the amendment.

(d) Amended contract filings may be submitted with additional information that may be appropriate for the Department's review.

§ 301.314. Department review.

(a) The Department may review the HMO materials filed, to examine the transference of risk and other matters that may affect the financial condition of the HMO.

(b) In evaluating the financial condition of an HMO, the Department will ascertain whether one or more of the following are present in an IDS contract:

(1) An appropriate provision similar to the hold harmless provision described in § 301.122 (relating to hold harmless), prohibiting the IDS and participating providers from billing HMO members.

(2) A provision for the maintenance of books, accounts and records by the IDS to assure that transactions, including the risk transfer, are clearly, accurately and completely disclosed.

(3) Appropriate terms permitting the HMO to assure itself of the financial viability and condition of the IDS throughout the term of the contract. These terms might include one or more of the following:

(i) A provision authorizing the HMO to access the IDS's books, accounts and records upon terms and conditions as the HMO and the IDS may agree.

(ii) A provision requiring that the IDS secure an audited financial statement on at least an annual basis and that the HMO receive the audited statement on an annual basis and interim unaudited financial statements from the IDS on a regular and ongoing basis.

(iii) A provision authorizing the HMO to receive information regarding the IDS's reserves so that the HMO may adequately evaluate its reserves.

(iv) A provision for the IDS to post a letter of credit or other acceptable financial security, in a reasonable amount as agreed upon between the HMO and IDS.

(v) A provision establishing a withholding of the fee in a reasonable amount as agreed upon between the HMO and IDS and which may be returned to the IDS under the terms of the contract.

(vi) A provision for the IDS to carry general liability insurance and for participating providers to carry professional liability insurance in an amount and from a carrier mutually acceptable to the HMO and the IDS.

(vii) A provision for the IDS to secure a surety bond to cover the IDS's performance under the contract.

(viii) A provision for the IDS to secure excess of loss insurance in an amount and from a carrier mutually acceptable to the HMO and the IDS.

(4) A provision prohibiting the assignment of any rights or obligations under the contract in the absence of the consent of the HMO.

(5) A provision granting the HMO the right to be advised of, and the right to object to, any subcontractor of the IDS with respect to services required to be performed by the IDS under the contract with the HMO.

(6) Appropriate provisions for the termination of the contract, including consideration of whether the HMO has the right to immediately terminate the contract upon a valid order issued by the Commissioner or other lawful authority.

(7) A provision setting forth the circumstances under which the HMO may institute an appropriate financial monitoring plan of the IDS.

(8) A provision requiring that the IDS carry appropriate insurance coverage, such as fidelity bonds covering IDS employes who handle HMO funds and workers' compensation insurance.

(9) A provision requiring that the IDS timely advise the HMO of relevant matters that may have a material effect on the IDS's ability to perform under the contract, including, for example, the following:

(i) Whether the IDS or a participating provider is subject to an administrative order, cease and desist order, fine or license suspension.

(ii) Whether legal action has been taken which may have a material effect on the IDS's financial condition or the IDS's ability to perform under the contract.

(c) The Department may seek additional information if one or more of the following exist:

(1) A contract by which 50% or more of the HMO's annual aggregate premium is transferred to a single IDS.

(2) Multiple contracts by which 75% or more of the HMO's annual aggregate premium is transferred to one or more IDSs.

(3) A contract with an IDS that has control of the HMO. The Department presumes that control exists if an individual or entity, directly or indirectly, owns, controls, holds with the power to vote, or holds proxies representing 10% or more of the voting securities of any other entity.

(4) A contract by which the claims processing, claims payment or claims adjudication functions are transferred to the IDS.

(5) A contract by which managerial control of the HMO's information system is transferred to the IDS.

(6) A contract when the HMO employs an individual who is also employed by the IDS.

(7) A contract when there is overlap between the officers or directors of the IDS and the HMO.

(8) A contract that contains a provision which might be construed as impeding or limiting the Department's authority to examine the books, accounts and records of the HMO and other persons under section 903(b) and (c) of The Insurance Department Act of 1921 (40 P. S. § 323.3(b) and (c)).

DEPARTMENT EXAMINATIONS

§ 301.321. Department examinations of HMOs.

(a) The Department is authorized to conduct financial examinations of HMOs under section 901 of The Insurance Department Act of 1921 (40 P. S. § 323.1).

(b) In its periodic financial examinations and other financial analyses of HMOs, the Department will continue to hold HMOs ultimately responsible for the liabilities arising under its subscriber agreements, regardless of whether the HMO has elected to contract with one or more IDSs to perform or arrange for the performance of services to HMO members.

(c) HMOs that contract with IDSs shall ensure that the HMOs remain able to meet their statutory financial reporting requirements, and otherwise comply with Department requests for information under section 11 of the act (40 P. S. § 1561) and section 903(a) of The Insurance Department Act of 1921 (40 P. S. § 323.1(a)).

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