



Virginia
Regulatory
Town Hall

Final Regulation Agency Background Document

Agency Name:	Department of Health (State Board of Health)
VAC Chapter Number:	12 VAC 5-407
Regulation Title:	Regulations for the Submission of Health Maintenance Organization Quality of Care Performance Information
Action Title:	Adoption of Regulations Requiring the Submission of Quality of Care Performance Information by Health Maintenance Organizations
Date:	March 21, 2003

Please refer to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99) , and the *Virginia Register Form, Style and Procedure Manual* for more information and other materials required to be submitted in the final regulatory action package.

Summary

Please provide a brief summary of the new regulation, amendments to an existing regulation, or the regulation being repealed. There is no need to state each provision or amendment; instead give a summary of the regulatory action. If applicable, generally describe the existing regulation. Do not restate the regulation or the purpose and intent of the regulation in the summary. Rather, alert the reader to all substantive matters or changes contained in the proposed new regulation, amendments to an existing regulation, or the regulation being repealed. Please briefly and generally summarize any substantive changes made since the proposed action was published.

The proposed regulations will address the annual submission by health maintenance organizations of the National Committee for Quality Assurance's Health Plan Employer Data and Information Set (HEDIS) as required by Chapter 897 of Section 31.2 of the Code of Virginia.

Changes made to the regulations since the publication of the proposed action address 1) the date of the biennial evaluation required by the Board of Health concerning the impact and effectiveness of collecting and making available the HEDIS data; and 2) VDH's deadline date for notifying HMOs of the process for data submission.

Changes Made Since the Proposed Stage

Please detail any changes, other than strictly editorial changes, made to the text of the proposed regulation since its publication. Please provide citations of the sections of the proposed regulation that have been altered since the proposed stage and a statement of the purpose of each change.

1. At 12 VAC 5-407-90 A., Process for Data Submission, the date for notifying HMOs of the process for data submission has been changed from March 1 to January 1 of each year.
2. At 12 VAC5-407-130, Biennial Evaluation, the date of the Board's evaluation has been changed from October 1 to January 15.

Statement of Final Agency Action

Please provide a statement of the final action taken by the agency: including the date the action was taken, the name of the agency taking the action, and the title of the regulation.

The State Board of Health adopted the HMO regulations at a regular meeting held on April 25, 2003.

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority, shall be provided. If the final text differs from that of the proposed, please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the final regulation and that it comports with applicable state and/or federal law.

Sections 32.1-276.3, 32.1-276.4, 32.1-276.5 and 32.1-276.8 of the Code of Virginia (as amended by Senate Bill 533, 2000 Act of Assembly, c. 897) grants the mandatory authority for the regulations.

Section 32.1-276.4 requires the State Health Commissioner to contract with a non-profit organization to “collect, compile, and publish Health Employer Data and Information Set (HEDIS) information or reports or other quality of care or performance information sets approved by the Board pursuant to 32.1-276.5, and submitted by health maintenance organizations or other health care plans.”

Section 32.1-276.5 of the Code requires that HMOs "shall annually submit to the Commissioner, to make available to consumers who make health benefit enrollment decisions, audited data consistent with the latest version of the Health Employer Data and Information Set (HEDIS), as required by the National Committee for Quality Assurance, or any other quality of care or performance information set as approved by the Board. The Commissioner, at his discretion, may grant a waiver of the HEDIS or other approved quality of care or performance information set upon a determination by the Commissioner that the health maintenance organization has met Board-approved exemption criteria. The Board shall promulgate regulations to implement the provisions of this section."

This section also requires that the Commissioner make available to consumers the HMO data. The State Board of Health is required to evaluate biennially the impact and effectiveness of the data collected.

Section 32.1-276.8 of the Code grants the Board of Health the authority to prescribe a tiered-fee structure based on the number of enrollees for each health maintenance organization to cover the costs of collecting and making available the data.

The final regulation differs from the proposed regulation only in two very minor ways that do not raise issues regarding statutory authority.

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the final regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.

For Virginia consumers who make health insurance decisions, it is often difficult to obtain information about the quality of health maintenance organizations (HMO). The proposed regulations will require the annual submission of quality of care data to the State Health Commissioner by HMOs. The quality of care data will be published via the internet by VHI, Inc. However, these regulations are not essential to protect the health, safety or welfare of the citizens of Virginia. The HEDIS data required by the regulations are available already at the web site of the National Committee for Quality Assurance (NCQA). Furthermore, these regulations apply only to fully insured health plans regulated by the Commonwealth of Virginia. Self-funded plans are exempt from state regulation in accordance with ERISA. The state regulated plans are generally only purchased by small business employers and only 25% of insured Virginians belong to these plans. Small businesses seldom offer their employees a choice of HMOs, so it is not expected that many consumers will need to have the kind of data required by these regulations because these consumers will likely not have a choice of plans.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement of the regulatory action's detail.

The proposed regulatory action will detail the quality performance measures required of HMOs, the process for submission of data, the tiered-fee structure, and the criteria for exemption by the Commissioner. The decision on the appropriate performance measures will represent a consensus of insurance brokers, HMOs, small and large employers, consumer advocates, and agency health policy staff with expertise in managed care and HEDIS.

Issues

Please provide a statement identifying the issues associated with the final regulatory action. The term "issues" means: 1) the advantages and disadvantages to the public of implementing the new provisions; 2) the advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please include a sentence to that effect.

The primary advantage to the public is that these regulations permit the implementation of the legislation requiring the publication of quality performance information about HMOs licensed in Virginia. This information is useful to consumers or businesses wishing to compare the quality performance of HMOs. The only potential disadvantage to consumers or businesses would be if the compliance with these regulations were to prove sufficiently burdensome to the HMOs to cause an increase in premiums. The advantages to the Department of Health in publishing this information is that it reinforces VDH's role in monitoring the quality of health plans. The disadvantage is that the fees paid by the HMOs for this initiative will likely not be applied to VDH's costs, primarily staff time, in the administration of this initiative, which will likely be burdensome. The fiscal impact of these regulations listed in the TH-02 was approximately \$7,000 in initial implementation costs and \$2,000 per year for ongoing operational expenses.

Public Comment

Please summarize all public comment received during the public comment period and provide the agency response. If no public comment was received, please include a statement indicating that fact.

COMMENT # 1

Section 12 VAC 5-407-100: Modify the fee schedule and combine Fee sections A and B: M.D. Individual Practice Association, Inc. and Optimum Choice, Inc. support reasonable fees to make

health care performance data available to consumers. The National Committee for Quality Assurance (NCQA) is also very supportive of state initiatives to educate consumers regarding the quality of health care. As a result, HEDIS data is now available to the Commonwealth at a nominal cost. Sharing the cost of purchasing the HEDIS data among the HMOs submitting information to NCQA is now obsolete and creates confusion about the fees contained in the regulation. Therefore, we recommend the following deletions and modifications to Fees A and B.

12 VAC5-407-100. Fees

A. For each HMO required to provide information pursuant to this chapter, the board shall prescribe a reasonable fee to cover the cost of collecting and making available such data. The Commissioner may purchase HEDIS data or other quality of care or performance information set on behalf of all the actively licensed HMOs in the Commonwealth that are participating in HEDIS and divide the cost among the HMOs. Each HMO shall pay an equal share of the cost to the Board for the purchase of the HEDIS data directly from NCQA. The remainder of the cost associated with making the data available shall be divided among the participating HMOs in a tiered format based on the number of enrollees per HMO. The cost associated with making the data available shall be divided among the participating HMOs in a tiered format based on the number of enrollees per HMO. The fees described in subdivision A, shall not exceed \$3,000 per HMO per year.

B. Fees described in subdivision A, above shall not exceed \$3,000 per HMO per year.

C.B. The payment of...

The remaining language in Fee sections A and B would be combined into a single section with the following language:

12 VAC5-407-100. Fees

A. For each HMO required to provide information pursuant to this chapter, the board shall prescribe a reasonable fee to cover the cost of collecting and making available such data. The cost associated with making the data available shall be divided among the participating HMOs in a tiered format based on the number of enrollees per HMO. The fees shall not exceed \$3,000 per HMO per year.

AGENCY RESPONSE

This comment appears to be based on a much earlier draft of the regulations than was put forth for public comment. The current section on fees appears in the current draft regulations as follows:

12 VAC 5-407-100. Fees

A. For each HMO required to provide information pursuant to this chapter, the board shall prescribe a reasonable fee to cover the cost of collecting and making available such data. Each HMO shall pay for the cost to the board for purchase of the HEDIS data directly from NCQA.

The remainder of the cost associated with making the data available shall be divided among the participating HMOs in a tiered format based on the number of enrollees per HMO.

B. Fees described in subdivision A, above, shall not exceed \$3,000 per HMO per year.

COMMENT # 2

2. Section 12 VAC 5-407-130: Change the Completion date of the Biennial Evaluation from October 1st of the measurement year to January 15th of the following year: M.D. IPA and OCI support the biennial evaluation by the Board of Health (12 VAC 5-407-130). However, we recommend that the completion date for this evaluation be moved back from October 1st to January 15th of the following year. This would give the Board of Health a more reasonable time frame to complete the study with all of the tools available to analyze health care performance data, such as NCQA’s Quality Compass. The proposed language is:

12 VAC5-407-130. Biennial Evaluation

A. The Board shall evaluate biennially the impact and effectiveness of collecting and making available HEDIS or any other quality of care or performance information set, and the appropriateness of the fee structure. This evaluation shall be completed by October 1 January 15 of the following year.

AGENCY RESPONSE

The requested change is reasonable and will be incorporated into the draft regulations.

COMMENT # 3

It is not clear from the regulation if reporting in Virginia must be based on the members residing in the state or if reporting based on the accredited entity will be acceptable. We urge the Board to accept the reporting of combined data based on NCQA accreditation and the practice of surrounding jurisdictions. Doing so will maintain consistency in how health plans currently report and reduce the processing burden and additional cost to those plans that report HEDIS data on a national basis.

AGENCY RESPONSE

A primary concern of VDH in the drafting of the regulations for HMO quality data reporting was that the proposed regulations impose as little administrative burden on the health plans as possible. For that reason, HEDIS or other data reporting is not required to be specific to operations or covered lives in Virginia. HEDIS data based on the “accreditable entity” is acceptable.

COMMENT #4

Section 32.1-276.5 of the Code requires that HMOs annually submit audited data consistent with the latest version of the HEDIS as required by NCQA. To reduce the overall HEDIS reporting

burden, NCQA has instituted a measure rotation strategy that allows a health plan to rotate selected commercial and Medicaid measures on a biennial basis. The rotation of measures allows health plans to use the audited and reportable rate from the prior year's data collection in lieu of collecting the measure for the current measurement year. Each year, NCQA specifies a list of selected measures that are eligible for two-year reporting. The measures are rotated every other year on a structured schedule. As the regulation is silent on this matter, we request clarification of whether the state will adhere to the NCQA rotation schedule.

AGENCY RESPONSE

VDH, in the interest of administrative simplicity for the health plans, has always planned to conform HMO reporting requirements to those adopted by NCQA, and will require the same measures to be reported.

COMMENT # 5

12VAC 5-407-50 A. Reporting Requirements for HMO Data. This section states that an HMO shall make available HEDIS or any other quality of care or performance information set, or a subset thereof. We suggest that this section be modified to add the words, "as approved by the Board", after "information set" as contained in the statute. As currently worded, this section appears to grant broader authority than intended by the underlying statute in determining what performance information set may be used.

AGENCY RESPONSE

In the most current draft of the proposed regulations, 12 VAC 5-407-50 in its entirety reads:

12 VAC 5-407-50. Reporting Requirements for Health Plan Data

- A. Every HMO shall make available to the commissioner those HEDIS measures, or a subset thereof, that are required by NCQA for accreditation.
- B. The board may contract directly with NCQA to purchase the selected HEDIS measures on behalf of the HMOs.

The concerns expressed in Comment # 5 appear to be addressed in 12 VAC 5-407-60, as follows:

12 VAC 5-407-60. Exception to HEDIS Reporting

- A. The board may approve and require quality of care data other than the HEDIS measures provided that reasonable notice is given to the HMOs in writing.

COMMENT # 6

12 VAC 5-407-90 A., Process for Data Submission. We respectfully suggest that the date for notifying HMOs of the process for data submission be moved back from March 1 to January 1 of each year based upon the timeline used by NCQA.

AGENCY RESPONSE

The requested change is reasonable and will be incorporated into the draft regulations.

COMMENT # 7

12VAC5-407-100 B. Fees. While we realize the underlying statute provides for a tiered fee structure subject to a cap of \$3000.00 we hope that any imposition of fees will be minimal in nature. As a national health plan Aetna currently reports HEDIS data to 25 Departments of Health, Departments of Insurance and business coalitions without any cost to the Company. In a time of rising health costs we believe that every effort should be made to implement this process without additional charges to carriers.

AGENCY RESPONSE

It is the agency's intention to ensure that fees assessed health plans will not exceed the costs associated with the purchase of the data and making it available to the public.

COMMENT # 8

We suggest that the following information be provided to health plans either as part of the regulation or in a bulletin:

- List of NCQA HEDIS measures required, using the NCQA name for the measure
- The format in which the data should be provided (i.e. NCQA Data Submission Tool, EXCEL spreadsheet provided by the state)
- Advice as to whether an electronic and/or hard copy is acceptable
- List of audit submission requirements (i.e. Final Audit Statement, Audit Designation Table, etc.)
- Due dates for submission of all materials

AGENCY RESPONSE

The agency will notify the health plans of these and other specifications for data submission in accordance with the regulations but will not amend the regulations to include specific data submission requirements.

COMMENT # 9

VAHP supports the flexibility given to the Board of Health (12 VAC 5-407-60 A) to require the submission of a data set in lieu of HEDIS if warranted. Though we do not anticipate such a change being necessary or desirable in the near future, VAHP respectfully requests that the Board only consider such a step thoughtfully and in direct consultation with the industry, as well as other affected parties.

AGENCY RESPONSE

The agency benefited from the collaboration and counsel of the Virginia Association of Health Plans in the development of the proposed regulations and hopes that the Association will be actively involved in the implementation of the proposed regulations.

COMMENT # 10

VAHP recognizes that the statute provides for a tiered fee structure capped at \$3,000 “to cover the costs of collecting and making available” the quality of care data or performance information set. Though our members remain frustrated over unnecessary duplication in fees (one plan stated that it submits HEDIS data to state regulators or business coalitions in 25 states and does not pay a fee in any of these circumstances), it is our hope that the imposition of fees will be minimal.

AGENCY RESPONSE

It is the agency’s intention to ensure that fees assessed health plans will not exceed the costs associated with the purchase of the data and making it available to the public.

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or crosswalk - of changes implemented by the proposed regulatory action. Include citations to the specific sections of an existing regulation being amended and explain the consequences of the changes.

1) In Section 12 VAC 5-407-90 A., Process for Data Submission, the date for notifying HMOs of the process for data submission was changed from March 1 to January 1 of each year based upon the timeline used by NCQA.

2) In Section 12 VAC 5-407-130, the completion date of the Biennial Evaluation was changed from October 1st of the measurement year to January 15th of the following year. Evaluation required by the Board of Health concerning the impact and effectiveness of collecting and making available the HEDIS data; and 2) VDH's deadline date for notifying HMOs of the process for data submission. Enter Statement Here

Family Impact Statement

Please provide an analysis of the regulatory action that assesses the impact on the institution of the family and family stability including the extent to which the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one’s spouse, and one’s children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

These regulations will have no impact on the family unless they prove to be sufficiently burdensome to the HMOs to precipitate an increase in the cost of insurance premiums.