



Ref: PC – 01/10/00

1st October 2000

To: Health Authorities (England) Chief Executive
Health Authorities (England) Directors of Primary Care
NHS Regional Directors
All General Practices (England)
Primary Care Trusts Chief Executive
Primary Care Groups Chief Executive
Local Medical Committees

ELECTRONIC PATIENT MEDICAL RECORDS IN PRIMARY CARE

Changes to the GP Terms of Service

Summary

This letter announces a change to the General Practitioner's (GP's) terms of service effective from 1 October 2000 the effect of which will allow GPs to maintain part or all of their patient medical records on a computer system if they so wish. The regulations are contained in the National Health Service (General Medical Services) Amendment (No.4) Regulations 2000 - SI 2383. It also provides guidance to Health Authorities who are now required to approve all requests from a GP to maintain electronic patient medical records.

The changes are also mirrored in the attached amendment to paragraph 20 of Schedule 1 to the Directions to Health Authorities and Primary Care Trusts Concerning the Implementation of Pilot Schemes (Personal Medical Services).

Action

Health Authorities are asked to:-

- implement, in consultation with their Local Medical Committee, the mechanisms which will allow the efficient discharge of their responsibility to approve requests to introduce electronic record keeping;
- implement, in consultation with their Local Medical Committee, the procedures that will operate should they wish to remove their authority to allow a GP to maintain electronic records;
- identify a senior officer who will have responsibility for approving requests to maintain electronic records;

- note that because of the provisions of the directions made by the Secretary of State on 25 March 1999 as to the functions of Primary Care Groups and the Primary Care Trusts (Functions) Regulations 2000, decisions on electronic record keeping cannot be delegated to a Primary Care Group (PCG) or Primary Care Trust (PCT).

General Practitioners:-

- who are currently maintaining electronic patient records should obtain health authority approval in line with their new terms of service.

Background

1. The National Health Service (General Medical Services) Amendment (No.4) Regulations 2000 SI 2383 amends paragraph 36 of Schedule 2 to the National Health Service (General Medical Services) Regulations 1992 (the terms of service) to allow a GP to keep the patient medical records maintained by virtue of his terms of service either (regulation 36(2)):-
 - (i) on forms supplied to him for the purpose by the Health Authority; or
 - (ii) by way of computerised records, or
 - (iii) in a combination of those two ways.
2. GPs cannot maintain these patient records electronically without the written consent of their health authority (regulation 36(3)), where more than one health authority is involved the consent should be made by the responsible health authority as defined in paragraph 72 of the Statement of Fees and Allowances.
3. There are a number of further conditions which must be met, these are:-
 - (i) the computer system on which the electronic records are maintained must be accredited to RFA99 standards (regulation 36(4(a))) ;
 - (ii) the computer security measures and audit functions must be enabled (regulation 36(4(b)));
 - (iii) the doctor(s) is aware of, and has signed an undertaking that he will have regard to, the guidelines contained in “Good Practice Guidelines for General Practice Electronic Patient Records (regulations 36 (4(c))).

In addition regulation 36(9) provides that where a doctor keeps computerised records he shall not disable, or attempt to disable, either the security measures or the audit function referred to in regulation 36(4(b)).

4. If a health authority is not satisfied that these conditions are being met they should not give their consent to the maintenance of electronic patient medical records (regulation 36(4)).
5. A health authority’s existing right to request patient medical records is maintained within the new amendment (regulation 36(7)). Health authorities will wish to consider whether or not they are prepared to receive these records from GPs who

maintain electronic records other than in a paper format. GPs must return records in a paper format unless the health authority consents to receive the record in an alternative media (regulation 36(8)) and health authorities will individually need to decide how they will exercise this discretion. For this purpose “paper format” would include a record made up of written material and material contained within a computer print out.

6. In exercising their right to accept records other than in paper format health authorities may decide not to exercise this function until such time as there are proper processes to facilitate the electronic transfer of patient records from GP to GP (see paragraphs xi. – xv.)
7. Any GP wishing to maintain electronic patient medical records must ensure that they are properly registered under the prevailing data protection legislation, health authorities would be well advised to check this as part of the consent process.
8. This change delivers the commitment in Information for Health (paragraph 2.57) to remove the contractual requirement for GPs to retain paper records. This is a clear enabler in delivering the vision of electronic patient and health records outlined in the strategy but in itself it does not remove the need to view the creation of electronic records in the context of a seven year strategy which includes long term targets designed to deliver comprehensive electronic record keeping within the NHS.

Guidance

Guidance is attached at the Annex.

Statutory Instrument and Good Practice Guide on Electronic Patient Records

Copies of the Statutory Instrument and Good Practice Guide on Electronic Patient Records (along with an electronic copy of this letter) can be found at www.doh.gov.uk/gpepr . Requests for hard copies and any further queries should be forwarded to Mr John-Jo Oldham at the address below:

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Mike Farrar
Head of Primary Care
NHS Executive

Guidance

- i. Health authorities must recognise that this change to the GP's terms of service is permissive, it does not introduce any degree of compulsion into the process, it does not in itself set targets nor does it require a sudden change from paper records to electronic records. Individual practices will decide how to implement electronic record keeping locally. Approaches to historic patient information may differ but as a minimum a summary of the patient's medical history will need to be included in the electronic record before paper records cease to be used in routine patient care.
- ii. Health authorities have a key role to play in satisfying themselves that any practice is ready to safely maintain electronic patient medical records. It is not our intention to set a pre-determined process that must take place before consent is given and authorities are strongly advised to agree suitable processes locally with their Local Medical Committees as long as the resultant agreements are commensurate with the health authority's responsibilities under the new legislation. As part of this process health authorities will need to decide at what point in the evolution of electronic record keeping a GP will be required to seek consent for electronic record keeping (see section 3.5 of the Good Practice Guidelines). Whilst the content of patient medical records has largely been a matter for the clinical judgement of individual GPs once it is proposed to keep significant clinical data solely in electronic form health authority consent must be obtained.
- iii. To provide assurances that the standard of electronic record keeping will be consistent across a general practice all the constituent GPs should sign the undertaking required by regulation 36(4). It is difficult to envisage a situation where health authority consent could be given for electronic record keeping where some members of the practice were not prepared to participate.
- iv. Health authorities will need to apply the new regulations to practices that are already maintaining electronic records. Where the authority are satisfied that the practice is safely maintaining electronic patient records and the regulatory criteria are met the health authority should issue their approval as soon as is practical. There will be practices which meet these requirements but who are not currently using RFA99 accredited computer systems. RFA99 systems are only just becoming available and it would be unproductive to try to force such practices back onto paper based records. The authority should work with the practice to plan a sensible migration to properly accredited software. The aim should be to have all these existing electronic practices operating with the required health authority consent and with RFA99 accredited computer systems before 31 March 2001.
- v. There is no new central requirement to monitor ongoing standards of record keeping but health authorities should be aware that they can withdraw their consent for electronic patient records. This would be an extreme course of action and again authorities would be strongly advised to agree procedures with their Local Medical Committees. As a minimum these could have links to local complaints processes or investigations into poor record keeping (paragraph 17 to the NHS (Service Committee and Tribunal) Regulations 1992 as amended).

- vi. As part of this change the Department has issued with this circular a Good Practice Guide for General Practice Electronic Patient Records which is endorsed by both the General Practitioners Committee of the British Medical Association and the Royal College of General Practitioners. Any GP introducing electronic patient records is required to sign an undertaking that he will have regard to, the guidelines contained in “Good Practice Guidelines for General Practice Electronic Patient Records” (regulation 36(4(c))). GPs and health authorities should recognise that adherence to these guidelines is required to ensure that the critically important patient medical record is maintained in a safe environment, is maintained accurately and has an accurate history which can be reproduced as necessary.
- vii. Achieving these standards will require a package of measures to support the GP/practice in areas such as:-
 - a. preparing the practice’s clinical processes to facilitate accurate and compatible records, for example agreeing clinical coding protocols such as the use of READ codes;
 - b. providing for an extensive training process for all the practice staff;
 - c. resourcing additional staff time to translate paper records into an electronic format, for example trained summarisers;
 - d. allowing resources to cover the costs associated with employing a more highly skilled workforce;
 - e. providing any related computer upgrades.
- viii. GP/Practices will want to be able to look to their health authority/Primary Care Trust in developing and resourcing such a programme. Everyone needs to recognise that finance, time, informatics skills etc are finite and this will limit the pace of change in any health authority. It would be unwise to try and move too quickly simply to create, for example, a PCG where every practice maintains electronic records where this cannot be supported by a business case and adequate resources. It must always be the GPs within a general practice that make the decision to maintain electronic patient records; the health authorities role is to approve appropriate applications and to ensure, within the limits of its resourcing processes, that the practice receives the support it then requires to safely make the transition from paper to electronic records.
- ix. In developing their Local Implementation Strategies health authorities will wish to take into account the pace at which resources will be needed to support the migration to electronic patient records. Resources for this exercise will need to be prioritised using a combination of modernisation fund monies and the unified budget allocations. There will be no specific resource allocation issued as part of this change.

PMS Pilots

- x. The changes are also mirrored in the attached amendment to paragraph 20 of Schedule 1 to the Directions to Health Authorities and Primary Care Trusts

Concerning the Implementation of Pilot Schemes (Personal Medical Services). PMS Pilot sites will therefore be required to obtain the same health authority permissions as GMS sites.

Electronic Record Transfer

- xi. As an integral part of this process the NHS Information Authority have commissioned work to develop, in the first instance, a software specification which will allow the transfer of a structured text message which would encapsulate the electronic patient medical record. This facility is likely to be available in twelve months time and we will write to you further about its implementation when there are more details.
- xii. This work will be followed by a second phase which will develop a software specification that will allow the transfer of a fully coded electronic patient medical record that can be automatically assimilated into the records held by the new practice. At this stage we would estimate this will be available in three years time.
- xiii. It is possible that some GP system suppliers may separately develop mechanisms that will deliver the limited capability of being able to transfer patient medical records between identical GP clinical systems. Any GP who considers using such functionality will need to ensure that adequate confidentiality and security measures are in place to support the transfer and that the practice he is sending records to both has the capability to accept the electronic transfer and is willing to accept the record in this way. Any GP choosing to use this type of transfer functionality must recognise that, until further notice, the process has to be seen as a duplicate of the normal record transfer processes. They are still required to transfer the entire patient medical record via the health authority in accordance with current procedures (see paragraph xv below).
- xiv. In addition to developing the GP clinical software to support GP to GP record transfer work will also be required to look at the impact on the administrative processes supported by the existing record transfer mechanisms. For example, the need to update patient demographic detail in health authority and other central records. These issues will also be looked at in the coming months and where practical adjustments made, and publicised, before the national GP to GP record transfer software specification is released for use.
- xv. However, as an interim measure pending the release of the national software specification and associated guidance, to ensure that complete medical records are transferred whenever a patient transfers from one GP to another a full patient record should continue to be forwarded to the new GP, normally via the health authority as now, with the existing Lloyd George envelope (FP5, FP6, FP111). The record should normally consist of all relevant paper records, including copies of associated word processed or scanned documents which make up the totality of the patient record. All RFA 99 accredited systems are required to have the facility to allow a user to print out the entire patient record which can then be included with the Lloyd George envelope to complete the patient record.

**HEALTH ACT 1999
NATIONAL HEALTH SERVICE (PRIMARY CARE) ACT 1997
NATIONAL HEALTH SERVICE ACT 1977**

**DIRECTIONS TO HEALTH AUTHORITIES IN ENGLAND CONCERNING
THE IMPLEMENTATION OF PILOT SCHEMES (PERSONAL MEDICAL
SERVICES) (AMENDMENT)**

The Secretary of State, in exercise of the powers conferred upon him by sections 17 and 17A of the National Health Service Act 1977 (a), and section 6(1) of the National Health Service (Primary Care) Act 1997(b), hereby gives the following Directions:

Application, commencement and interpretation

1. —1. These Directions shall come into force on 1 October 2000 and amend the Directions to Health Authorities and Primary Care Trusts Concerning the Implementation of Pilot Schemes (Personal Medical Services) 2000(c).

(1) In these Directions-

“the principal Directions” means the Directions to Health Authorities and Primary Care Trusts Concerning the Implementation of Pilot Schemes (Personal Medical Services) 2000;

“computerised records” means records created by way of entries on a computer.

(2) These directions extend to Health Authorities and Primary Care Trusts in England.

Amendment of principal Directions

2. —(3) For paragraph 20 of Schedule 1 to the principal Directions, there shall be substituted –

“Patient Records

20. –(1) Adequate records of the illnesses and treatment of pilot patients shall be kept by the pilot scheme provider –

(a) on forms supplied to him for the purpose by the Health Authority; or

(b) subject to sub-paragraphs (2) and (3), by way of computerised records,

(a) 1977 c.49. Section 17 was substituted and section 17A was inserted by the Health Act 1999 (c.8), section 12. The 1977 Act has effect in relation to services provided in accordance with Part I of the 1997 Act by virtue of section 9 of that Act.

(b) 1997 c. 46.

or in a combination of those two ways.

(2) Where a pilot scheme provider proposes to keep computerised records, he shall first obtain the written consent of the Health Authority.

(3) The Health Authority shall consent to a pilot scheme provider's application to keep computerised records if it is satisfied that -

- (a) the computer system upon which he proposes to keep them has been accredited by the Secretary of State or another person on his behalf in accordance with "General Medical Practice Computer Systems - Requirements for Accreditation - RFA99"(d);
- (b) the security measures and the audit function incorporated into the computer system as accredited in accordance with sub-paragraph (a) have been enabled; and
- (c) the pilot scheme provider is aware of, and has signed an undertaking that he will have regard to, the guidelines contained in "Good Practice Guidelines for General Practice Electronic Patient Records"(e),

and the Health Authority may withdraw its consent if it ceases to be so satisfied.

(4) Where a pilot scheme provider keeps computerised records he shall, as soon as possible following a request from the Health Authority, allow the Health Authority access to the information recorded on his computer system by means of the audit function referred to in paragraph (3)(b).

(5) A pilot scheme provider shall send the records relating to a patient to the Health Authority-

- (a) as soon as possible, at the request of the Health Authority; or
- (b) where a person whose name is included in the list of pilot patients dies, before the end of the period of 14 days beginning with the date on which he was informed by the Health Authority of the death, or (in any other case) before the end of the period of one month beginning with the date on which he learned of the death.

(c) These directions were published by the National Health Service Executive on 9 May 2000. Copies may be obtained by writing to Room 7E01, Quarry House, Quarry Hill, Leeds LS2 7UE.

(d) This was published by the National Health Service Information Authority- in October 1999. Copies may be obtained by writing to the National Health Service Information Authority, 15 Frederick Road, Birmingham B15 1JD.

(e) These guidelines were published by the National Health Service Executive on 31 August 2000. Copies may be obtained by writing to PC GPMS, Room 7E24, Quarry House, Quarry Hill, Leeds LS2 7UE .

(6) To the extent that a patient's records are computerised records, a pilot scheme provider complies with sub-paragraph (5) if he sends to the Health Authority a copy of those records –

- (a) in written form; or
- (b) with the written consent of the Health Authority, in any other form.

(7) The Health Authority shall consent to the transmission of information other than in written form for the purposes of paragraph (6)(b) if it is satisfied with the following matters—

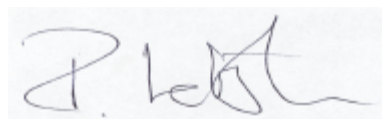
- (a) the pilot scheme provider's proposals as to how the record will be transmitted;
- (b) the pilot scheme provider's proposals as to the format of the transmitted record;
- (c) how the pilot scheme provider will ensure that the record received by the Health Authority is identical to that transmitted; and
- (d) how a written copy of the record can be produced by the Health Authority,

and the Health Authority may withdraw its consent if it ceases to be satisfied as to any of the above matters.

(8) Where a pilot scheme provider keeps computerised records he shall not disable, or attempt to disable, either the security measures or the audit function referred to in paragraph (3)(b).”.

Signed by authority of the Secretary of State for Health

26th September 2000



Rob Webster
Department of Health
A Member of the Senior Civil Service