June 2014



Focus on vaccines and immunisations

Guidance for GPs



Focus on vaccines and immunisations

Updated June 2014

These guidelines refer to England, Scotland and Wales, unless where it is specified that the guidance or regulations differ in any of the devolved nations. For ease of reading, most of the links will refer to English guidance, but links to the devolved nations have been added to the end of the document for information. For information about the arrangements in Northern Ireland, please contact <u>NIGPC@bma.org.uk</u>.

Introduction

Since April 2004, under the new GMS contract, vaccines and immunisations have been funded through various mechanisms dependent on which services a practice wishes to provide. Payment may be through the:

- global sum
- enhanced services (ES)
- quality and outcomes framework (QOF)
- private income for some travel immunisations

The regulations regarding the NHS provision of immunisations can be traced back to the original 'Red Book'¹ regulations of the 1960s. Under the Red Book, most vaccines and immunisations were paid on an item-of-service basis and additionally the main childhood immunisations had a target-based remuneration. The regulations were written to cover the immunisations available at that time and consequently do not reflect today's clinical practice. In 2004, the new GMS contract² took those regulations and carried them into the new contract as an additional service. Consequently everything in the Red Book was transferred unchanged and included in the global sum rather than the previous item of service system. The fact that these regulations had become out of date because of changes in the vaccines themselves and continued to contain inappropriate references, such as smallpox, did not prevent them being carried over into the new contract. The amendments to the Additional Services section of the NHS Regulations 2004 which were made in 2012 (in England), now more accurately reflect current practice, attempt to clarify the previous regulations to make them fully up to date but were not intended to introduce any new work. Further changes to the regulations have been made in 2013 and 2014.

Occupational vaccinations

The new wording of the regulations makes it clearer that certain at-risk groups have been included, e.g. rabies immunisation for laboratory workers, and typhoid immunisation for hospital doctors who might come in to contact with the disease. This has always been the case (as set out in the Red Book), but it is now more clearly set out in the new regulations.

Although only the vaccine itself is remunerated via the global sum, there is no funding within the global sum to provide the occupational health aspects of case finding, risk assessing and documenting. If there are any attempts to transfer occupational health commitments to practices then we expect there to be appropriate remuneration for these services. Please note our comments in <u>Appendix 1</u> where we feel this applies. Practices in England and Wales can purchase these vaccines and claim reimbursement through the personal administration.

¹ 'Red Book' - Statement of fees and allowances payable to general medical practitioners in England and Wales is unavailable online.

²webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Healthcare/Primarycare/Primarycarecontracting/GMS/DH_4125639

Hepatitis B

Hepatitis B raises quite a number of complex issues which are covered in a separate guidance Focus on hepatitis B immunisations (which replaced Hepatitis B immunisation for employees at risk (2005)). It is not generally covered in the regulations because it is not included in the GMS contract's additional services. However, there is a new scheme which was introduced in April 2014 for giving and checking up on hepatitis B for new born babies at risk, which attracts specific funding.

The global sum

The global sum pays for essential and additional services to patients on your list. Regulation 15 of the NHS Contract Regulations (England, Scotland and Wales) defines essential services³, and paragraph 5 provides an obligation to provide ongoing treatment and care for all registered patients and temporary residents taking account of their specific needs. This may include immunisation against disease where it is in the patient's interest.

Within the global sum there is payment for two additional services:

Vaccines and immunisations - all necessary vaccines and immunisations are set out in part 2 of Annex B of the Statement of Financial Entitlements (SFE) England⁴ and part 4 of the SFE in Scotland, although this excludes the influenza and pneumococcal immunisation DES and certain travel vaccines that can be charged for privately. The full list of vaccines and immunisations is attached at Appendix 1 and Appendix 2 (for travel) and the relevant NHS Regulations at Appendix 3.

Childhood vaccines and immunisations – providing all necessary childhood vaccines and immunisations under the Childhood Immunisations Scheme as set out in section 11 of the SFE (England)4, part 3 of SFE in Scotland and Wales⁵. These are also listed as part of Appendix 1.

Childhood vaccinations have changed significantly over the years. There are gains and losses; many single vaccines have been combined although the funding for each component remains in the global sum (e.g. diphtheria, pertussis, tetanus, polio and Hib); whilst on the other hand new vaccines have been introduced with either no additional global sum funding (e.g. MMR and Men C at 3 months) or as new payments outside of the global sum (e.g. PCV and booster Hib/Men C). In 2013 and 2014 a number of changes were made added to the childhood immunisations schedule, which falls in to this category, and they have been added to the Enhanced Services section of this guide.

In 2013 an enhanced services programme was introduced in England. Wales and Scotland in response to local outbreaks. The programme required practices to identify patients aged 10-16 who were unvaccinated and invite them to receive a MMR vaccine. This requirement was retired 31 March 2014 (in England, Scotland⁶ and Wales). Payment for this was covered in the Global Sum and continues to be the case for any patients aged 10-16 who selfpresent or are identified on an opportunistic basis.

Additionally patients over 16 who had no record of vaccination, who self-present to the practice requesting vaccination, were to be vaccinated. This element continues from 1 April

³ Regulation 15 of the NHS Regulations 2004 <u>www.legislation.gov.uk/uksi/2004/291/regulation/15/made</u> ⁴www.gov.uk/government/publications/nhs-primary-medical-services-directions-2013

www.wales.nhs.uk/sites3/page.cfm?orgid=480&pid=6070 www.sehd.scot.nhs.uk/cmo/CMO(2014)03.pdf

2014 for another year and this requirement has now been added to the SFE. Note that there may also be local schemes in place for MMR immunisations for children older than 16 that are not covered by this additional service and so would need funding separately. Further information about the MMR catch up programme is available on the BMA website.

Should a practice for whatever reason feel unable to provide these additional services a percentage of the global sum will be extracted from the practice's global sum. For vaccines and immunisations this will be a 2% reduction and for childhood immunisations and preschool boosters there will be a 1% reduction (SFE, Part 1 (2.5)4).

Enhanced services

There are a number of enhanced services that GPs can provide in relation to vaccines and immunisations. The provision of the influenza vaccine, for example, is now provided under a seasonal influenza and pneumococcal immunisation enhanced service (ES) in England. From 1 April 2014, the seasonal flu programme will mirror the at-risk groups in the Green Book to include pregnant women, but excluding 2-4 year olds (as they are covered under the childhood flu programme), and a service specification⁷ has been published outlining the arrangements.

The Department of Health (England) now recommend that the following at-risk groups should receive the influenza vaccination:

- those aged 65 or over at the end of the financial year
 - those patients of any age suffering from:
 - \circ chronic respiratory disease (including asthma and COPD⁸)
 - chronic heart disease 0
 - chronic liver disease \circ
 - chronic neurological disease 0
 - o chronic renal disease
 - diabetes mellitus \circ
 - immuno-suppression due to disease or treatment 0
- those living in long-stay residential or nursing homes •
- pregnant women.
- carers •
- children age 2 to 4 years⁹ •
- frontline healthcare professionals

Health care professionals should generally get vaccinated at their place of work, via occupational health services. However, in 2013, it was agreed that (in England and Wales), for payment proposes, locum GPs should get vaccinated where they are registered as patients, rather than where they work and practices can claim payment for this via CQRS.

Further information about the at-risk groups and the recommendations are available in the tripartite letter (England)¹⁰ for 2014-15 (equivalent letters in Wales¹¹ and Scotland¹²). For pneumococcal immunisation the at-risk group includes those aged 65 or over, as well as

⁷ www.england.nhs.uk/wp-content/uploads/2014/05/childrens-flu-prog-serv-spec.pdf

⁸ The DES in Scotland says chronic respiratory disease (including asthma), but the CMO letter says chronic respiratory disease (including asthma on inhaled steroids) - claims will be made according to DES rather than the CMO letter.

⁹ This was expanded to all preschool children (2-5 year olds and Primary School years P1-7) in Scotland from 1 April 2014; In Wales, this also includes year 7 secondary year school pupils. ¹⁰www.gov.uk/government/publications/flu-immunisation-programme-2014-to-2015

¹¹ wales.gov.uk/docs/phhs/publications/130816fluen.pdf (2013)

¹² www.sehd.scot.nhs.uk/cmo/CMO(2014)12.pdf

those under 65 who meet the (at risk criteria in the Green Book, which was introduced (in England) in April 2014 and will apply from 1 August 2014, to resolve a historic anomaly between the enhanced service and the recommended cohort). Although pneumococcal immunisations are often targeted at those attending the annual influenza campaigns, there is a difference (apart from the fact that most patients only need pneumococcal immunisation just the once).

Since 1 October 2012, a **temporary programme of pertussis vaccinations for pregnant women** has been in place in England¹³, Wales¹⁴, and Scotland.

In April 2013, the **routine shingles vaccination** for patients aged 70, but not yet 71, on 1 September 2013, was introduced as part of the 2013/14 GMS contract changes. A **catch-up programme** was also agreed and effective from 1 September 2013 in England¹⁵, Wales¹⁶ and Scotland¹⁷, which has now been extended until 31 March 2015. It was initially rolled out to all registered patients aged 79 years on 1 September 2013, and has been extended to those aged 78 and 79 but not 80 on 1 September 2014.

As from 1 April 2014, patients aged 17 to 25 at any time during the financial year 14/15 who are attending university (or higher education) for the first time and self-present to the practice requesting vaccination and have not been immunised since age 10, should be offered a **MenC vaccination**¹⁸. Prospective students will receive notification via UCAS about this and vaccination should be done by 31 October 2014.

Childhood immunisations

There have been several changes to the childhood immunisation programme in 2013 and 2014.

Childhood influenza

In addition to the children in the at-risk groups who would be vaccinated under the influenza programme, from 1 September 2014, practices should also vaccinate children between two and four years of age as part of a comprehensive vaccination programme on a pro-active call and recall basis¹⁹. In Wales, this includes year 7 secondary year school pupils who missed their vaccination in school and in Scotland, as from 1 April 2014, this also includes all preschool children²⁰.

Hepatitis B for newborn babies at risk

As from 1 April 2014, in England, newborn babies at risk of Hepatitis B (i.e. whose mother has Hepatitis B) should receive four doses of the Hepatitis B vaccination. The programme is intended to identify these newborn babies and ensure they receive vaccination within the first 3 months after birth and fourth dose at the age of 1. Guidance is available in the Vaccination and immunisation programmes 2014-2015 - Guidance and audit document²¹.

¹³ <u>bma.org.uk/practical-support-at-work/contracts/independent-contractors/pertussis-vaccination</u>

¹⁴ wales.gov.uk/docs/phhs/publications/130712cmoen.pdf

¹⁵bma.org.uk/-

[/]media/Files/PDFs/Practical%20advice%20at%20work/Doctors%20as%20managers/Managing%20your%20servi ces/shinglescatchupprog2013_specification.pdf

¹⁶ wales.gov.uk/docs/phhs/publications/130813cmoletter15shinglesvaccineen.pdf

¹⁷ www.sehd.scot.nhs.uk/pca/PCA2014(M)04.pdf

¹⁸www.gov.uk/government/publications/menc-vaccination-schedule-planned-changes-from-june-2013

¹⁹www.england.nhs.uk/wp-content/uploads/2014/05/childrens-flu-prog-serv-spec.pdf

²⁰ http://www.sehd.scot.nhs.uk/cmo/CMO(2014)13.pdf

²¹bma.org.uk/practical-support-at-work/gp-practices/vaccination

Meningitis C

From 1 June 2013, in England, Scotland and Wales²², practices should no longer give the second priming dose at age of 16 weeks²³. This has now been replaced by an adolescent booster dose to be given in schools, and a booster dose for freshers was also introduced in 2014 as per the enhanced services section above.

<u>Rotavirus</u>

The oral rotavirus vaccine was introduced (in England²⁴, Wales²⁵ and Scotland) as part of the childhood immunisation schedule on 1 July 2013, to be given at 2 and 3 months of age.

In addition, in response to local or national outbreaks, catch-up campaigns may be introduced to boost the immune status of susceptible populations.

Further information and guidance on vaccinations and immunisations, including the more recent changes to the childhood immunisations schedule, is available on the BMA website vaccinations and immunisations pages.

Quality and Outcomes Framework (QOF)

Whether a practice is commissioned for the influenza and pneumococcal DESs or not, a practice may acquire Quality and Outcomes Framework (QOF) points for vaccinating patients within specific disease groups. The following indicators reward doctors for vaccinating patients against flu: CHD007, STIA009, DM018 and COPD007 (and equivalent in the devolved nations).

The influenza enhanced service has an item of service payment per vaccination that is provided whether the target is met or not. Any practice that completes the influenza enhanced service successfully will also automatically qualify for QOF points. If a practice does not take on the enhanced service but still vaccinates patients in disease groups they can earn QOF points.

The latest QOF guidance can be found on the BMA website <u>QOF pages</u>.

Travel immunisations

Under the Red Book a limited number of travel immunisations were provided on the NHS. In 2004 the new GMS contract took those regulations and carried them into the new contract as an additional service. Consequently everything in the Red Book was transferred unchanged and included in the global sum rather than the previous item of service system. This failed to recognise the change in range of immunisations and the nature of foreign travel making the regulations difficult to interpret.

This became clearer with the publication of Annex B, Part 2 of the SFE in 2012. For example Hepatitis A (referred to by its old name of "Infectious Hepatitis" in the Red Book) was

wales.gov.uk/topics/health/cmo/publications/cmo/2013/vaccine/?lang=en

²³ www.gov.uk/government/publications/menc-vaccination-schedule-planned-changes-from-june-2013

²⁴ www.gov.uk/government/collections/rotavirus-vaccination-progarmme-for-infants

²⁵ www.wales.gov.uk/docs/phhs/publications/130524rotavirusen.pdf

previously paid under item of service for one dose as that was all that was available before the active vaccine was introduced in 1993. Although it was always intended to cover courses of treatment this was not specified under the old regulations, but the new regulations helpfully states that "a *course* of immunisation should be offered".

The following travel immunisations are not prescribable as part of NHS services and are not remunerated by the NHS as part of additional services:

- Yellow Fever
- Japanese B encephalitis
- Tick borne encephalitis
- Rabies

The following travel immunisations that can be given as *either* NHS or as a private service:

- Hepatitis B (single agent) any dose
- Meningitis ACWY (quadrivalent meningococcal meningitis vaccine; A, C, Y and W135)

One significant area of uncertainty remains in that the regulations do not specify when these immunisations should be given on the NHS or as a private service. In fact it still remains a decision that comes down to the policy of individual practices. Naturally, in those areas where local policies have been agreed with the LMC which rationalise or specify NHS provision, those policies should be respected. Many practices provide hepatitis B as part of a combined A+B vaccination rather than as a single agent, and this has been the focus of local attention as this must be given as an NHS service. Ultimately the decision still resides with the practice. We would remind practices that there is no funding within GMS for hepatitis B for travel although in England and Wales reimbursement through the personally administration scheme can be claimed (but not if the vaccine is given on a private basis)

The list of travel immunisations available on the NHS is available in <u>Appendix 2</u>. Practices may choose to opt-out of providing the additional vaccines and immunisations service, but will as a result have their global sum abated by 2%. Practices opting out of the additional service will also not be able to charge their registered patients for travel vaccines which are available on the NHS.

Schedule 5 of the NHS Regulations (see <u>Appendix 4</u>) lists all those services for which practices *may* choose to charge patients. This includes all vaccines requested for travel that are not paid for by the NHS. It also permits charging for prescribing or supplying malaria chemoprophylaxis and for other drugs and kits to be used for illnesses arising when abroad.

Detailed information about travel immunisations is available in <u>Focus on travel</u> <u>immunisations</u>

Further information

BMA guidance on vaccinations and immunisations is available on the BMA website

Any queries about this guidance should be sent to info.gpc@bma.org.uk

Department of Health (England) immunisation information for health professionals and immunisation practitioners

The Green Book - Immunisation against infectious disease

NHS Choices guidance on childhood immunisations

Health Protection Agency (HPA) - Public Health England guidance on immunisation

Guidance and regulations in the devolved nations

Wales:

wales.gov.uk/topics/health/cmo/publications/cmo/2014/?lang=en (English)

wales.gov.uk/topics/health/cmo/publications/cmo/2014/?skip=1&lang=cy (Welsh)

Scotland:

www.scot.nhs.uk/publications/publication.asp?name=&org=&keyword=immunisation&catego ry=-1&number=10&sort=tDate&order=DESC&Submit=Go

Northern Ireland:

www.dhsspsni.gov.uk/index/phealth/php/immunisation.htm

www.dhsspsni.gov.uk/index.htm

APPENDIX 1 – Vaccines and immunisations for persons not travelling abroad

Disease	At-risk groups who should be vaccinated and number of doses
Anthrax	Persons at an identifiable risk of contracting anthrax should receive four doses of the vaccine (plus an annual reinforcing dose). This would mainly be those who come into contact with imported animal products.
	Also see note about occupational health ²⁶ .
Diphtheria, Tetanus and Polio	a) Children under age of 6 years should be offered immunisation in accordance with the Childhood Immunisations Scheme (as referred to in Section 11)4 [,]
	 b) Those aged 6 years or over who have not had the full course of immunisation, or whose immunisation history is unknown should be offered either: i) a primary course of three doses plus two reinforcing doses at
	suitable time intervals; or
	ii) as many doses as required to ensure that a full five dose schedule has been administered , whichever is clinically appropriate ²⁷ .
Hepatitis A	Persons in residential care or those residing in an educational establishment who are exposed to a high risk of infection and for whom vaccination is recommended by the local Director of Public Health.
	A course of immunisation (the number of doses required will be dependent upon the chosen vaccine and should be sufficient to provide satisfactory long-term protection against the disease).
	This is an example where changes of the vaccine available (from single dose immunoglobulin to hepatitis A vaccine) mean that there are changes to the practice of administration requiring more than one dose.
Measles, Mumps and Rubella (MMR)	a) Children under 6 years should be offered MMR immunisation in accordance with the Childhood Immunisations Scheme (as referred to in Section 11 and Annex 1)4,
	b) Children under 6 years should be offered a second dose as a follow up to the dose given under the Childhood Immunisations Scheme
	c) Children from age 6 to 15 years who have not previously received two doses or whose immunisation history is incomplete or unknown should be offered one or two doses (whichever is clinically appropriate)
	d) Women who may become, but are not pregnant and are sero-negative should be offered one or two doses (whichever is clinically appropriate)
	e) Male staff working in ante-natal clinics who are sero-negative should be offered one or two doses (whichever is clinically appropriate).
	Also see note on occupational health ²⁶ and 'whenever clinically appropriate' ²⁷ .

Based on Part 2 of Annex B of the SFE4 with comments from the GPC.

²⁶ The new wording of the regulations makes it clearer that certain at-risk groups have been included. However, there is no funding within the global sum to provide the occupational health aspects of case finding, risk assessing and documenting. This is explained in more detail on page 2-3 of this guidance. ²⁷ The regulations use the words 'whichever clinically appropriate' to ensure that immunisation schedules for

patients are completed, with primary and booster immunisations.

Meningococcal Group C (Men C)	 Children under 6 years should be offered meningococcal immunisation in accordance with the Childhood Immunisations Scheme (as referred to in Section 11)4 and offered the pneumococcal and Hib/MenC booster vaccine in accordance with Section 13. (b) Persons aged between 6 and not yet 25 years who have not been previously been immunised with conjugate Men C vaccine, or whose immunisation history is incomplete or unknown, are to be offered one dose of conjugate Men C vaccine. (c) Persons who attain the age of 25 years in the period commencing 1 April 2014 and ending 31 March 2015 who have not previously been immunised with conjugate Men C vaccine, or whose immunised with conjugate Men C vaccine.
	one dose of conjugate Men C vaccine.
Rabies (pre exposure)	Three doses of the Rabies vaccine are to be offered to:
	a) laboratory workers handling rabies virus
	b) bat-handlers
	 c) persons who regularly handle imported animals, such as those at animal quarantine stations at zoos
	 at animal research centres and acclimatisation centres at ports where contact with imported animals occurs and this may include certain HM Revenue and Custom offices persons carrying agents of imported animals who are veterinary or technical staff in animal health
	d) animal control and wildlife workers who regularly travel in rabies enzootic areas
	e) health workers who are a risk of direct exposure to body fluids or tissue from a patient with confirmed or probable rabies.
	Reinforcing doses are to be provided at recommended intervals to those at continuing risk (according to the 'Green Book' ²⁸).
	Also see note regarding occupational health ²⁶
Typhoid	A course of typhoid vaccine is to be offered to
	a) hospital doctors, nurses and other staff likely to come into contact with cases of typhoid
	b) laboratory staff likely to handle material contaminated with typhoid organisms.
	The number of doses (including reinforcing doses) required depends on the chosen vaccine and is to be offered so as to provide satisfactory protection against the disease.
	Also see note regarding occupational health ²⁶ 26

²⁸ <u>www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book</u>

Paratyphoid ²⁹	No vaccine currently exists for the immunisation of paratyphoid.
Smallpox ³⁰	The smallpox vaccine exists but is not currently available to Contractors.

Appendix 2 - Vaccines and immunisations for persons travelling abroad

Contractors who offer and provide immunisations for travel must have regard to the guidance set out in the 'Green Book'²⁸ and the information provided by NaTHNaC³¹.

Disease	Groups or persons affected who should be vaccinated
Cholera	A course of immunisation should be offered to persons travelling
	(a) to an area, as defined by NaTHNaC, where they may risk exposure to infections as a consequence of being in that area or(b) to a country where it is a condition of entry to that country that persons have been immunised.
	The appropriate course of immunisation is dependent on age and will consist of an initial course and a subsequent reinforcing course of immunisation. If more than two years have elapsed since the last course, a new course of immunisation should be commenced.
Hepatitis A	A course of immunisation should be offered to persons travelling to areas, as defined by NaTHNaC, where the degree of exposure to infections is believed to be 'high' ³² .
	Persons who may be at a higher risk of infection include those who (a) intend to reside in an area for at least three months and may be exposed to hepatitis A during that period; or (a) if exposed to hepatitis A, may be less resistant to infection because of a pre-existing disease or condition or who are at risk of developing medical complications from exposure.
	The number of doses (two or three) of the vaccine required depends on the chosen vaccine and should be sufficient to provide satisfactory long-term protection against the disease.
Poliomyelitis 33	 a) A course of immunisation (using an age appropriate combined vaccine) should be offered to persons travelling (i) to an area, as defined by NaTHNaC, where they may risk exposure to infection as a consequence of being in that area; or (ii) to a country where it is a condition of entry to that country that persons have been immunised.
	 (b) Children under the age of 6 years are to be offered immunisation in accordance with the Childhood Immunisations Scheme (as referred to in Section 11)4 (c) Persons aged 6 years and over who have not had the full course of immunisation or whose immunisation history is incomplete or unknown are to be offered, either (i) a primary course of three doses plus two reinforcing doses at suitable

²⁹ No vaccine is currently available for paratyphoid. Should a vaccine become available a review would be considered and consultation would be required in accordance with section 87 of the National Health Service Act ^{2006.} ³⁰ Routine vaccination of smallpox is not appropriate and no vaccine is available for use in general practice.

Should it become appropriate to vaccinate, a review and consultation would be required (section 87 of the NHS 2006). ³¹ National Travel Health Network and Centre (NaTHNaC) <u>www.nathnac.org</u>

³² The NaTHNaC website only refers to risk which is assumed be 'significant'. The definition in the regulations is 'high', as 'significant' does not have any meaning in law and cannot be in the regulations. Since the risk can never be zero the wording in the regulations has to remain 'high'. ³³ Note that although the SFE only refers to poliomyelitis, the only form given is the combined Td/IPV vaccine of

tetanus, diphtheria and polio.

	time intervals; or (ii) as many doses as required to ensure that a full five dose schedule has been administered, whichever is clinically appropriate.
Typhoid	A course of typhoid vaccine should be offered to persons travelling:
	 (a) to an area, as defined by NaTHNaC, where they may risk exposure to infection as a consequence of being in that area; or (b) to a country where it is a condition of entry to that country that persons have been immunised.
	The number of doses (including reinforcing doses) required depends on the chosen vaccine and is to be offered so as to provide satisfactory protection against the disease.

APPENDIX 3 – Extract from Additional Services section of NHS Regulations

The National Health Service (General Medical Services Contracts) Regulations 2004

SCHEDULE 2, Regulation 16 (Amended 30 April 2012)³⁴

ADDITIONAL SERVICES

Vaccines and Immunisations

4. - (1) This paragraph applies to a contractor whose contract includes the provision of vaccines and immunisations but does not apply in the case of the provision of –

- (a) childhood immunisations; and
- (b) the combined Haemophilus influenza type B and Meningitis C booster vaccine.
- (2) A contractor must comply with the requirements in sub-paragraph (3) and (4).
- (3) The contractor must -

(a) offer to provide to patients, all vaccines and immunisations (other than those mentioned in sub-paragraph (1)(a) and (b)) of the type and in the circumstances which are set out in the GMS Statement of Financial Entitlements;

(b) taking into account the individual circumstances of the patient, consider whether immunisation ought to be administered by the contractor or other health professional or a prescription form ought to be provided for the purpose of the patient self-administering immunisation;

(c) provide appropriate information and advice to patients about such vaccines and immunisation;

(d) record in the patient's record, any refusal of the offer referred to in paragraph (a);

(e) where the offer is accepted and immunisation is to be administered by the contractor or other health professional, include in the patient's record -

(i) the patient's consent to immunisation or the name of the person who gave consent to immunisation and that person's relationship to the patient;

- (ii) the batch numbers, expiry date and title of the vaccine;
- (iii) the date of administration;

(iv) in the case where two vaccines are administrated by injection, in close succession, the route of the administration and the injection site of each vaccine;

³⁴ The National Health Service (Primary Medical Services) (Miscellaneous Amendments) Regulations 2012 , Schedule 2: <u>http://www.legislation.gov.uk/uksi/2012/970/regulation/5/made</u>

- (v) any contraindications to the vaccine; and
- (vi) any adverse reactions to the vaccine; and

(f) where the offer is accepted and the immunisation is not to be administered by the contractor or other health professional, issue a prescription form for the purpose of self-administration by the patient.

(4) The contractor must ensure that all staff involved in the administration of immunisations are trained in the recognition and initial treatment of anaphylaxis.

(5) In this paragraph "patient's record" means the record which is kept in accordance with paragraph 73 of Schedule 6.

Childhood vaccines and immunisations

5. - (1) A contractor whose contract includes the provision of childhood vaccines and immunisations shall comply with the requirements in sub-paragraphs (2) and (3).

(2) The contractor shall -

(a) offer to provide to children, all vaccines and immunisations of the type and in the circumstances which are set out in the GMS Statement of Financial Entitlements,

(b) provide appropriate information and advice to patients and, where appropriate, their parents, about such vaccines and immunisations;

(c) record in the patient's record kept in accordance with paragraph 73 of Schedule 6 any refusal of the offer referred to in paragraph (a);

(d) where the offer is accepted, administer the immunisations and include in the patient's record kept in accordance with paragraph 73 of Schedule 6 -

(i) the name of the person who gave consent to the immunisation and his relationship to the patient;

(ii) the batch numbers, expiry date and title of the vaccine;

(iii) the date of administration;

(iv) in a case where two vaccines are administered in close succession, the route of administration and the injection site of each vaccine;

- (v) any contraindications to the vaccine or immunisation; and
- (vi) any adverse reactions to the vaccine or immunisation.

(3) The contractor shall ensure that all staff involved in administering vaccines are trained in the recognition and initial treatment of anaphylaxis.

APPENDIX 4 – Extract from Fees and Charges section of the NHS regulations³⁵

The National Health Service (General Medical Services Contracts) Regulations 2004

SCHEDULE 5, Regulation 24

FEES AND CHARGES

1. The contractor may demand or accept a fee or other remuneration -

(a) from any statutory body for services rendered for the purposes of that body's statutory functions;

(b) from any body, employer or school for a routine medical examination of persons for whose welfare the body, employer or school is responsible, or an examination of such persons for the purpose of advising the body, employer or school of any administrative action they might take;

(c) for treatment which is not primary medical services or otherwise required to be provided under the contract and which is given -

(i) pursuant to the provisions of section 65 of the Act (accommodation and services for private patients), or

(ii) in a registered nursing home which is not providing services under that Act,

if, in either case, the person administering the treatment is serving on the staff of a hospital providing services under the Act as a specialist providing treatment of the kind the patient requires and if, within 7 days of giving the treatment, the contractor or the person providing the treatment supplies the Primary Care Trust, on a form provided by it for the purpose, with such information about the treatment as it may require;

(d) under section 158 of the Road Traffic Act 1988 (payment for emergency treatment of traffic casualties);

(e) when it treats a patient under regulation 24(3), in which case it shall be entitled to demand and accept a reasonable fee (recoverable in certain circumstances under regulation 24(4)) for any treatment given, if it gives the patient a receipt;

(f) for attending and examining (but not otherwise treating) a patient -

(i) at his request at a police station in connection with possible criminal proceedings against him,

(ii) at the request of a commercial, educational or not-for-profit organisation for the purpose of creating a medical report or certificate,

(iii) for the purpose of creating a medical report required in connection with an actual or potential claim for compensation by the patient;

(g) for treatment consisting of an immunisation for which no remuneration is payable by the Primary Care Trust and which is requested in connection with travel abroad;

(h) for prescribing or providing drugs, medicines or appliances (including a collection of such drugs, medicines or appliances in the form of a travel kit) which a patient requires to have in his possession solely in anticipation of the onset of an ailment or occurrence of an injury while he is outside the United Kingdom but for which he is not requiring treatment when the medicine is prescribed;

³⁵ <u>http://www.legislation.gov.uk/uksi/2004/291/schedule/5/made</u>

(i) for a medical examination -

(i) to enable a decision to be made whether or not it is inadvisable on medical grounds for a person to wear a seat belt, or

- (ii) for the purpose of creating a report -
 - (aa) relating to a road traffic accident or criminal assault, or
 - (bb) that offers an opinion as to whether a patient is fit to travel;

(j) for testing the sight of a person to whom none of paragraphs (a), (b) or (c) of section 38(1) of the Act (arrangements for general ophthalmic services) applies (including by reason of regulations under section 38(6) of that Act);

(k) where it is a contractor which is authorised or required by a Primary Care Trust under regulation 20 of the Pharmaceutical Regulations or paragraphs 47 or 49 of Schedule 6 to provide drugs, medicines or appliances to a patient and provides for that patient, otherwise than by way of pharmaceutical services or dispensing services, any Scheduled drug;

(I) for prescribing or providing drugs or medicines for malaria chemoprophylaxis.